An Exploration of the Clinical Practice of Rheumatology Specialist Nurses Undertaking Consultations with Patients Starting Methotrexate

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Abstract

Background

Rheumatology nursing roles have evolved over the last 25 years to include educating patients prior to commencing drugs such as Methotrexate in consultations. The expansion of their role has not been supplemented by specific training in order to prepare them for this undertaking. Thus, this study was developed to explore how Rheumatology Specialist nurses gained knowledge about consulting with patients on Methotrexate, how they delivered information to patients, and to identify elements of their consultation for further development.

Methods

This was a mixed-methods practice based study undertaken in three phases. Training, confidence and knowledge were explored with a questionnaire, which constituted Phase I. Phase II explored the lived experiences of the nurses with semi-structured interviews. Phase III explored the interaction between the nurses and patients during a consultation which was video-recorded and analysed using qualitative and quantitative approaches, with the interaction scored against items in the Calgary Cambridge consultation model.

Findings

The results of the survey (n=97) and the semi-structured interviews findings (n=6) revealed significant variability in training received by Rheumatology Specialist nurses. Confidence took three to 12 months to develop and was related to experience, knowledge and training, with nurses expressing a clear desire for more training. Written information was used by all participants during consultations, usually in the form of the Methotrexate information booklet, which had some benefits, including allowing the nurses to structure their consultations, ensuring that all of the information in the booklet was given to patients.

However, it also had the disadvantage of becoming the nurses' agenda which dominated the consultation, leading to overloading the patients with information and restricting discussion and questions from the patients. Analysis of consultation videos (n=10) supported these findings, demonstrating that whilst all of the important information from the booklet was given, there was a lack of involvement during the consultation of the patient agenda such as ideas, concerns and expectations, with little checking by the nurses to ensure the patients understood the information given. The effect of limited time was apparent. Cues from patients were often ignored or missed which may have been as a result of perceived time pressures or lack of confidence in dealing with questions. The comparison of the nurses' consultations with the Calgary Cambridge consultation model showed variations in the nurses' scores. It also raised new observations such as in those consultations which scored higher, the nurses used more illustrative and fewer batonic gestures, whilst the patient did the opposite.

Conclusions

Whilst Rheumatology Specialist nurses are clearly doing many things well, the education of patients starting drugs such as Methotrexate could be improved by training aimed at improving consultation techniques with the adoption of a modified Calgary Cambridge model consultation technique. Such an approach would benefit from further research to identify whether it results in improving patients' involvement in the consultation process. The findings from this thesis have led directly to the development of "Top Tips", published online by Versus Arthritis, to guide nurses during their consultations when giving information to patients about Methotrexate. Further work will include writing a handbook that aims to give nurses more knowledge about how to conduct a consultation with patients based on the Calgary Cambridge consultation model.

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Preface

I have a background in working with Rheumatology patients as a Registered Nurse. I took some time out of nursing to work abroad at the end of 1999, when I returned to the UK in 2004, I took up a post as a staff nurse in a Rheumatology outpatient clinic. Much had changed since the days of working on busy Rheumatology wards in the 1980s and 1990s and I found that most patients were now treated as outpatients.

There have been significant changes in the nursing role over the last 30 years especially in Rheumatology and a survey by the Royal College of Nursing (RCN) reported that nurses are now doing many roles that were previously carried out by doctors (Royal College of Nursing 2009). Even the role of the Health Care Assistant (HCA) has changed enormously, now carrying out phlebotomy, independently running clinics and setting up sterile fields (Griffiths and Robinson 2010, Robinson, Heslop et al. 2016). When I returned to work, I found myself having to educate patients starting disease modifying antirheumatic drugs (DMARDs) with which I was unfamiliar, and for which my training consisted of watching a nurse give the education from a pre-printed sheet of A4 paper. Each drug had a different coloured sheet, and I was told to just read from the sheet. It took me months to feel confident to give this education, and I increased my knowledge by gleaning information from my nurse colleagues, reading the Summary of Product Characteristics for each drug and listening to the Rheumatologists in the department. I reflected on this experience and concluded that, with formal training, I would have developed in that role much more quickly and I would have been more effective.

It also became apparent that there were a number of other issues to consider that were not immediately obvious. It was clear that the service side required some facts to be transferred to the patient around safety of taking the drugs and to ensure that patients took the drugs as prescribed. This required documentation that it had been done correctly and the document was signed by the nurse and the patient to confirm this. I felt that this documentation represented a disclaimer, so that if errors occurred, it was documented that the correct processes had been undertaken. I personally became more concerned with the education process that we were undertaking with the patients. I began to question how

much information they actually absorbed from the education activity, how much knowledge they actually took away with them and whether they fully understood the implications of taking the medication. My nurse training and my experience as a ward nurse had not prepared me for this. Whilst nurses have always been regarded as educators, I realised that we were not really equipped to carry this out as effectively as we could. I also wondered if other Rheumatology departments had a different and more effective method of conducting this transfer of knowledge to patients.

The science of communication is a complex area of study. I have described elements of the communication process which are pertinent to this thesis in the literature review (Chapter 2). I observed that my colleagues who were performing the same role as myself, varied considerably in their style and enthusiasm for this role and in the amount of time they took to convey the information to the patients. Prior to commencing my PhD, I asked my colleagues to time every Methotrexate education consultation that they did over a three-week period. I decided to focus on one drug, and chose Methotrexate as it is the most common drug used in Rheumatology. In our Rheumatology service, all patients who were prescribed Methotrexate or indeed, any DMARD, had their education session on that day. Patients were not given a specific appointment; everything was done on the same day as their consultation with the Rheumatologist. It was therefore difficult to plan the number of education sessions which could be carried out in one clinic. (This approach is different to the approach taken by The Rheumatology Service, which was studied in this thesis. In this service, patients were prescribed their DMARD then were sent dedicated appointment times with a Specialist Nurse when they would be given their education session). During the three weeks the nurses recorded their timing of their education session. Twenty-eight patients started Methotrexate for the first time. The same nurse performed ten of those education sessions, a second nurse carried eight out and three other nurses performed the other ten sessions, so five nurses in total took part. The average time taken was 13 minutes with a range from six to 20 minutes. Comparing the average time for individual nurses ranged from 12 to 16.5 minutes for the two main educators. One of the infrequent educators averaged only seven minutes. For those patients who were starting their first DMARD (some patients had been on other DMARDs before starting Methotrexate) the average time taken to deliver the education session was slightly longer at 14 minutes (6-20 minutes). For those patients

who were starting a second DMARD, the average was 12 minutes (range 7-15 minutes), which is slightly less. This could reflect an assumption that the patient knew more about DMARDs as they had already been prescribed one of these treatments.

The nurses were asked to estimate what percentage of the time was used for questions by the patients. This was only an average of 10% (range 0-50%) and eight patients asked no questions. I concluded that these consultations are clearly variable and that the patients may need more encouragement or empowerment to ask more questions. I concluded that an exploration of this interaction could produce information that may improve training, increase competence in the delivery of the education sessions and thus improve patient understanding resulting in more effective and safer use of the drug.

A further study which contributed to the concept of my PhD thesis was a survey of Methotrexate tolerability (Robinson, Gibson et al. 2016). I had noticed that patients on Methotrexate often did not like taking it. They described having a "Methotrexate day" where they felt "wiped out" for a day after taking it, or the patient would admit that they would take a "Methotrexate holiday" to have a break from it. I was also struck that the doctors didn't seem to be aware of this. The patients seemed much more open with the nurses than they were with their consultants. When I raised this I was told, "If they are prepared to take it and it is working then I am prepared to prescribe it. Why would I start a discussion about tolerability when they will still be on it?"

For the survey, with the help of one of the Rheumatology consultants, 100 consecutive patients who were on a stable dose of Methotrexate and planning to continue it, were asked to complete a questionnaire about efficacy and side effects. They also rated the severity on a visual analogue scale (VAS). 56% had at least one tolerability problem. When I presented this at the British Society for Rheumatology annual meeting (Robinson and Walker 2012) the general reaction from the delegates was that this was far higher than they would expect and thought these figures were incorrect. The survey was then repeated in six other Rheumatology centres across the UK, collecting questionnaire data from 50 consecutive patients from each of those sites. The results revealed that 56% was the lowest reporting of the number of issues patients had with Methotrexate. The highest tolerability issues in one

centre was reported as 85% of the patients taking it (Robinson, Gibson et al. 2016). Another interesting finding was that 51% of participants would be attracted to a regime that didn't include Methotrexate.

Because Methotrexate is a drug that has clear tolerability problems and a delayed onset of action, the effectiveness of the initial education given to patients is very important in order to ensure that patients are aware of these side effects and that they can become empowered to disclose the way they feel to their healthcare providers. If patients do not feel empowered to reveal issues they may have with their drugs, it could lead to issues around adhering to the treatment as prescribed.

In order to investigate this further, I was interested to establish the knowledge that patients established on Methotrexate had about the drug. This led to the development of a project I conducted with colleagues. We developed a study of knowledge about Methotrexate of people who had been on Methotrexate for at least two years and who were on no other conventional DMARD as this may have confused the patients. Methotrexate knowledge was tested with a Methotrexate Knowledge Questionnaire (MKQ), which we developed from the ARUK leaflet written for patients to learn about Methotrexate, and used by most nurses to guide counselling (Walker, Robinson et al. 2012). Fifty-two consecutive patients who fit the entry criteria were recruited and asked to complete the MKQ. Most were suffering from Rheumatoid Arthritis (RA) (89%) one had gut associated arthritis and the rest Psoriatic arthritis. Average age was 59 (range 24-84) and average duration of Methotrexate therapy was 6.2 years (range 2-15).

Average score on the MKQ was 12.9 out of a maximum 18 (range 6-18). All but one patient knew how to take the drug, but there was less certainty about how long it took to work. There was a range of knowledge about vaccinations, in line with the total score. Side effect knowledge was less good, with 12 patients (23%) not identifying shortness of breath as a side effect. Monitoring requirements were well known. Other worrying misconceptions included eight people (15%) thinking it was acceptable to become pregnant with 13 patients (25%) failing to answer the question. Twelve patients (23%) thought it was acceptable to be on antibiotics in conjunction with Methotrexate and four (8%) thought there was no limit around alcohol consumption.

We concluded that the patients were well aware of the practicalities of taking the drug. These are things that would be reinforced at each monitoring visit. However, there were deficiencies in some patient knowledge that might lead to sub-optimal immunisation, inappropriate action in the event of dyspnoea and worrying possibilities around pregnancy, alcohol and infections. More effective education and updates seemed to be required. This was presented at the BSR annual meeting as a poster (Walker, Robinson et al. 2012). The next phase of this journey towards my PhD was to question some of my nurse colleagues working in different Rheumatology Departments in the region and in other parts of the UK regarding the training they had to carry out this education role. I also wanted to determine whether there was a "Gold Standard" education programme that could be accessed by all Rheumatology Specialist nurses. However, I discovered that there was no gold standard professionally endorsed training for Rheumatology Specialist nurses. Thus, began the development of the proposal for this thesis. I wanted to determine firstly, what all nurses were doing in the UK, how they were trained to carry out their roles, how confident they were and to test their knowledge around DMARD drug treatments. The next phase was to explore the experience of giving education from the nurse's perspective more deeply. I decided to concentrate only on Methotrexate as this is the most widely used drug of choice to treat one of the most common conditions in Rheumatology; Rheumatoid Arthritis and all of the nurses would have experience in managing patients on this drug. Finally, I wanted to explore and analyse the actual process itself between the nurse and patient, which involved video-recording the consultation. Together with Dr David Walker, Consultant Rheumatologist, we successfully applied for funding from Arthritis Research UK (now known as Versus Arthritis), to carry out this work and I applied to Northumbria University to develop this into a PhD programme.

Acknowledgements

I have had amazing support from Northumbria University and particularly my supervisor Professor Nikki Adams, who has always been there for me, she is not just my supervisor, she is my friend. More recently, Dr Jason Scott has joined the team. He came in with a fresh approach and has guided me into different directions, which has enhanced this work. I would also like to mention two colleagues, Professor Sarah Ryan and Professor Andy Hassell, who have both been very supportive, interested and contributed to the three publications resulting from this thesis. I would finally like to mention Dr David Walker, Consultant Rheumatologist, my clinical supervisor, mentor and husband. His gentle encouragement and support kept me going throughout this long journey; I would not have been able to do it without him.

Dedication

It has been a long journey, during this time, my 15-year-old niece Abbie, was diagnosed with a rare and aggressive skin cancer, she lost her valiant fight aged 17 years. My father Joe, died three months later in September 2016. Those 2 1/2 years were lost in terms of working on my PhD, but Northumbria University allowed me to extend my study time. With only three months to go to finally submitting my completed thesis, the COVID-19 pandemic hit our country in 2020 and, as a nurse, my job was to support my colleagues, patients and the NHS, so again my submission was delayed. My mother Ellen, was diagnosed with lung cancer and died in April 2021 after a short but valiant fight. Their courage and determination in the face of such adversity gave me the strength and resolve to keep going when things got tough, so to their memories I dedicate this thesis.

Declaration

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my own work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others.

Any ethical clearance has been sought and approved and granted by NRES Committee North East – Sunderland and London-Brent Research Ethics Committee.

I declare the word count of this thesis is 81,164 words.

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Signature:

Date:

Chapter 1: Introduction

Rheumatoid Arthritis (RA) is an incurable chronic disease (Ward, Hill et al. 2007), the symptoms of which can have an enormous impact on a sufferer's daily life, affecting everyday activities such as domestic, work and leisure (Hill 2006). Management of the disease therefore requires a range of interventions such as physiotherapy, occupational therapy and pharmacological treatments which focus on relieving the symptoms of pain, swelling, joint stiffness and the provision of daily living aids resulting in the preservation of joints, minimising deformity and maintaining the activities of daily living (Hill and Ryan 2000, Hill 2006). Patients need an understanding of their disease, the value of the treatment they have been prescribed, the importance of adhering to that treatment and understand side effects so that they can be reported quickly. This knowledge helps patients to self-manage, ensures that drugs like Methotrexate are taken safely and involves them in the decision-making processes around their own treatment (Hill, Bird et al. 1991, Mäkeläinen, Vehviläinen-Julkunen et al. 2007, Salt and Frazier 2010). Hill et al (2001) carried out a randomised controlled trial comprising 200 patients with Rheumatoid Arthritis who had all been prescribed a disease modifying drug called D-penicillamine. Their aim was to explore the effects of patient education on drug treatment adherence which contributes to successful management of rheumatic disease. The chosen intervention of the study was a taught education programme about D-penicillamine, which was carried out by a Rheumatology Nurse Practitioner. Fifty-one patients received the intervention and 49 received standard care. The authors found that those patients receiving the education programme had significantly increased adherence levels to drug treatment, with 86% adhering compared to 55% not, after 12 weeks. Thus, patient education regarding taking specific drugs is of critical importance in adherence to drug treatment for chronic long-term conditions. However, this is dependent upon other factors such as knowledge and attitudes of the nurses themselves and how they communicate this information to patients in order to educate them about taking their drug therapy, which is the focus of this thesis.

Disease modifying anti-rheumatic drugs (DMARDs) reduce disease activity, joint destruction and improve long-term joint function (de Klerk, van der Heijde et al. 2003). In the field of

Rheumatology, toxic DMARDs such as Methotrexate have delayed effects and anticipated side effects for which patients are monitored. It is essential therefore, before commencing any drug for the patient to understand what the expected benefit is, how that will manifest and to know the risks of the intervention. Patients therefore require information prior to starting Methotrexate to allow them to take the medication more safely and effectively. Patients must have an understanding of illness, risks, and benefits of various treatment options in order to make informed decisions about medical care (Street Jr, Makoul et al. 2009). Clinicians also need to understand patient's values, preferences, and beliefs about health. But, achieving this status can be difficult because clinicians and patients often have different perceptions of health and illness (Street Jr, Makoul et al. 2009). Thus, the consultation between the nurses and patients when giving information about Methotrexate is an important process. Understanding how nurses are trained to carry out this role and exploring their perceived confidence led to the development of the aims of this study, which will be described below. Further, in order to understand and explore the training, knowledge base and confidence that nurses have, Phase I, a national survey was developed. Exploration of the experiences and perceptions of nurses conducting this role, led to the development of Phase II of this study, the semi-structured interviews. Finally, to further explore how nurses conduct their consultations when giving information about Methotrexate to patients, video-recording ten consultations formed the final Phase III of this study. These will be further discussed below.

1.1 The Research Question

Underpinned by the points above the research question was developed:
How do Rheumatology Specialist nurses gain knowledge about consulting with patients on Methotrexate and do they deliver the information to patients using a consultation technique, further can elements of their consultation be identified for development?
The research question was investigated by:

- Investigating, using a survey, the processes which nurses undertake to become knowledgeable about consulting with patients on Methotrexate and to understand how much knowledge and confidence they have in giving this information.

- Exploring, through semi-structured interviews, the nurses' experiences and perceptions of the delivery of information about Methotrexate to patients.

- Identifying, through video analysis of consultations, the processes used by the nurses in their consultations with patients when giving information about Methotrexate and how the consultations may be further developed using the Calgary Cambridge model.

The underpinning research philosophy was based on the three dimensions of critical realism using a mixed methods approach to collect the data and a phenomenological methodology to analyse the data.

1.1.1 Phase I Aims

The aims of the national survey were to explore the training that Rheumatology Specialist nurses had received for educating patients about Methotrexate. Further, to identify their confidence in conducting this role and to evaluate their knowledge around clinical situations relevant to Methotrexate use. The aim of this is to reveal if any further training is required.

1.1.2 Phase I Objectives

1. To obtain data regarding training, qualifications and experience through a national questionnaire.
2. To gauge nurses' views regarding confidence and the time it takes to become confidence in conducting this role.
3. To assess levels of knowledge Rheumatology Specialist nurses, have about Methotrexate.

1.1.3 Phase II Aim

To explore the nurses' experiences and perceptions of the delivery of information about Methotrexate to patients, using semi-structured interviews.

1.1.4 Phase II Objectives

1. To explore the training nurses had in order to carry out their role of giving information to patients on Methotrexate and how useful this was.
2. To understand how confident nurses are carrying out this role and how they feel about the training they had.
3. To understand how nurses, use written information to inform their consultations.
4. To explore how nurses, respond to patient cues putting them at the centre of care.

1.1.5 Phase III Aims

To investigate how nurses, deliver information about Methotrexate to patients, and how they ensure that patients have received and understood that information during the consultation process.

1.1.6 Phase III Objectives

1. Video record ten nurse/patient consultations.
2. Analyse the video recordings using the Medical Interaction Process and the Calgary Cambridge Model.
3. To understand the processes nurses, use in their interaction with the patients when giving information about Methotrexate.
4. To understand the processes nurses, use to ensure that patients have understood the information given.

1.2 The Structure of the Thesis

Chapter 1 gives a general introduction to the thesis and overview of the structure.

Chapter 2 presents the literature review providing a general overview of the topic and concepts as relevant to the whole thesis, with some in-depth background to the literature relevant to each phase presented at the start of each phases' chapter. Rheumatoid Arthritis is the disease which is most commonly treated by Methotrexate, therefore this disease is discussed thoroughly to understand the issues that patients have and why they need to have treatment. Particular reference will be made to Methotrexate as it is an important focus of this thesis and the evolution of the Rheumatology Specialist nurses' role will be discussed in order to explain the impact of the changing expectations placed on nurses. Patient education will be explored and the impact of shared decision-making as it is a central concept of the healthcare professional and patient interaction and should underpin practice. Further, an exploration of the literature around nurses' knowledge of Methotrexate will be undertaken to determine the impact of this on the information giving process and consultation models will also be reviewed to identify or adapt a model which could be applied to the nurse patient interaction within the context of this thesis.

Chapter 3 introduces the epistemological and ontological assumptions of the study which sit within critical realism. These are framed within the methodological approach of mixed methods. The chapter provides discussion on qualitative and quantitative research and how these can be combined using a mixed methods approach. Also addressed in this chapter are the ethical considerations of the study and the impact of insider research and a reflexive perspective of this researcher.

Chapters 4, 5 and 6 present the findings of the three phases of this study. Each of these chapters have a different data collection method which will be discussed.

Chapter 4 discusses Phase I which consisted of a national online survey and the resulting data was analysed using quantitative methods. A questionnaire survey was specifically developed to capture demographics, experience, knowledge of Methotrexate and delivery of information. It was piloted by ten Specialist nurses who work in the field of Rheumatology and was modified according to the findings. It was made available online and

targeted members of the Royal College of Nursing Rheumatology Forum members of which there are over 1,200 members. They were asked to complete the questionnaire and distribute it amongst their colleagues who give information to patients about Methotrexate, which allowed a wide spread of representation from Rheumatology Specialist nurses who carry out this role.

Chapter 5 addresses Phase II which consisted of the semi-structured interviews with Rheumatology Specialist nurses. The interviews were audio recorded and then transcribed. The data was analysed using a thematic methodological approach. The semi-structured interviews explored the feelings and perceptions of the nurses on how they conduct this role. This built on the national questionnaire aimed at exploring the general representation of how nurses are educated to conduct their role and how confident they feel in that role.

Chapter 6 explores Phase III of the study, the video-recordings of nurses giving information about Methotrexate to patients. Ten consultations between nurses and patients during the Methotrexate education process were undertaken. All of the nurses worked in the same Rheumatology service in one Trust. The nurse participants had a wide range of experience from less than two years' experience to more than ten years' experience. Participation was completely voluntary and consent was taken from both the nurses and patients prior to the video-recording. All resultant data was fully anonymized.

A qualitative analysis of the videos was undertaken using a thematic approach and they were also evaluated against the Calgary Cambridge consultation model. Additionally, the videos were analysed using a novel methodology, which had not been used to analyse nurse videos previously. The Medical Interaction Process System is based on the work of Roter (1991), which was developed to code the interactions between doctor and patient during a consultation process. Verbal coding is based on an "utterance" and non-verbal coding includes head nodding and smiling. The first ten minutes of each video recording were examined minute by minute and every verbal and non-verbal interaction was coded. This allowed for a detailed analysis of the interaction between nurses and patients.

Chapter 7 restates the aims and objectives of the study before providing a discussion of the findings. In this chapter the findings are discussed within the context of extant literature

and there is explanation of how these findings contribute to original knowledge. Discussion of these findings in relation to current practice and identification of areas requiring further research are presented along with the limitations of the study. Finally, this chapter discusses the next phase of this study based on the four publications which were generated by this work.

1.3 Original Contribution to Knowledge

The above will contribute to knowledge by exploring the processes through which nurses gain training to carry out their role of giving information to patients about Methotrexate. It will contribute to the extant literature regarding how nurses conduct their consultations with patients when carrying out this role and will reveal their experiences and perceptions of that role. This study will also contribute to the understanding of how nurses ensure that patients understand the information given to them and how they incorporate consultation techniques in their interactions with patients. Further, it will reveal possible aspects of their consultations which may need further training and identify a consultation model which could fill that gap.

Chapter 2: The Literature Review

2.1 Introduction

A narrative thematic approach, which was deemed relevant to this thesis, has been undertaken in the organisation of this review. The aim was to summarise the available evidence in each theme and develop the conceptual framework for this thesis. Therefore, this chapter will present an overview of the relevant literature relating to Rheumatoid Arthritis, including epidemiology, causes and its impact on the patient. Rheumatoid Arthritis is the focus as this is the disease area which is most commonly treated by Methotrexate, and thus is the overall focus of this thesis. Further review of the literature concerning the treatment of Rheumatoid Arthritis will also be presented in order to contextualise the range of treatments that are available and the breadth of knowledge Rheumatology Specialist nurses should have. Particular reference will be made to Methotrexate as this is the drug which is the focus of this thesis, specifically concerning the information-giving interaction process between nurses and patients. Literature on the evolution of the Rheumatology Specialist nurses will be reviewed in order to understand the background and influences which have led to the Rheumatology Specialist nurse today. A review of patient education with particular reference to shared decision-making will also be presented, as shared decision-making is a central concept of nurse-patient interaction and should be underpinning the evidence-based practice of Rheumatology Specialist nurses. Further, the literature on nurses' knowledge of Methotrexate will be reviewed to scrutinise what the existing evidence describes about nurses' knowledge of Methotrexate and to determine whether this could impact on the information giving process between nurses and patients. As with shared decision-making, consultation skills and models are also important for this thesis and therefore this review also focuses on the literature in this area. The consultation models will be examined with the aim of identifying a model which could be adapted to be used in the information giving process between nurses and patients, and indeed, the determine whether this has been carried out in Rheumatology or other chronic disease areas.

This widely themed review therefore sets out to identify the problems faced by the patient with Rheumatoid Arthritis and understand the treatment options with particular reference to Methotrexate. It also aims to put into context the amount of information which could be given to a patient, and therefore reveal the importance of ensuring that the patient understands and receives that knowledge in order to make informed decisions and choices. This literature review further focussed on the development of the Rheumatology Specialist nurse in order to understand the evidence base practice they employ to carry out their role and to reveal the opportunities available to them to broaden their knowledge base. Emphasis is placed on shared decision-making and consultation technique which will reveal the current evidence for incorporating good technique into practice. This review will then uncover those gaps in the literature which will become the focus of this thesis.

2.2 Rheumatoid Arthritis

The following sections will describe a brief history of Rheumatoid Arthritis, the epidemiology of the disease and possible causes. There will also be presented some descriptions of symptoms of this disease and the impact of these on sufferers. It is essential to consider this to be able to understand the significance of the impact of Methotrexate on controlling this disease.

2.2.1 History

Rheumatoid Arthritis is an auto-immune disease, and is the commonest form of inflammatory joint disease in the world (Tobón, Youinou et al. 2010). Historically, detecting Rheumatoid Arthritis in the archaeological record is difficult (Leden, Persson et al. 1988) because bone erodes and decays easily therefore leaving little archaeological evidence which makes it difficult to determine how long Rheumatoid Arthritis has been around. However, some periods have been more extensively studied, such as the Roman period and the quality of the archaeological remains indicate that life expectancy was lower than it is today at around 40 years (Montagu 1994), meaning that it is possible that not many people

would live long enough to develop Rheumatoid Arthritis. However, an examination of 41 skeletons from Ancient Mendes in Egypt which date back to the Old Kingdom (c. 2613-2181 BC), revealed that two skeletons exhibited signs of inflammatory joint erosions in their metacarpo-phalangeal joints (Mant 2014). Further, an examination of 416 skeletons from the Roman period in Britain (43 – 410AD) also showed inflammatory changes to the joints in the hands of two individuals (Thould and Thould 1983). However, as previously mentioned, the study of skeletal remains is not straightforward. Changes to bones can occur as a result of many different factors such as the soil, climate bacterial and fungal influence. A number of different conditions can cause joint changes such as gout, infection, or Marfan's Syndrome (Buchanan 1994). A study of Flemish paintings dating to 1400-1700 suggests that Rheumatoid Arthritis can be seen in five individuals on the paintings (Dequeker 1977), but this can be misleading because art is not always a reflection of reality and artistic styles changed throughout different periods of history (Honour and Fleming 2010). Some believe that Rheumatoid Arthritis is a New World (The Americas) disease which spread to the rest of the world population. Rothschild et al (1992) examined 129 skeletal remains of Native American men and women dating from 4,300 to 4,050 years ago and identified five women and two men with changes consistent with Rheumatoid Arthritis. They also examined archaeological remains from 63 archaic sites in the same area and did not find any evidence for Rheumatoid Arthritis. The first patients with a classical description of Rheumatoid Arthritis appear in the documentary evidence around 1800 when a French medical student called Augustin-Jacob Landre-Beauvais described these signs and symptoms in a series of patients for his doctoral thesis (Panush 2012). The description "Rheumatoid Arthritis" was introduced by Garrod in 1859 (1859). It does appear that Rheumatoid Arthritis was fairly uncommon prior to the 18th century. The 18th Century onwards saw the growth of trade and the Industrial Revolution. The sugar trade witnessed considerable growth and therefore the increase of periodontal disease, with a suggested pathogenic link between Rheumatoid Arthritis and periodontal disease (Kubetin 2010, Rosenstein, Scher et al. 2012). However, other researchers argue that the link is environmental (Hutchinson 2015) and a sharp increase in environmental pollutants after the Industrial Revolution may have contributed to the emergence of Rheumatoid Arthritis. It remains unclear when Rheumatoid Arthritis emerged; whilst it is possible that is has been around for hundreds of years, it appears that there was a significant increase in the incidence of the disease following the industrial

revolution which may have been the result of pollution, environmental changes, lifestyle transformations or genetic susceptibility (Shlotzhauer 2014).

2.2.2 Epidemiology

Rheumatoid Arthritis is a geographically widespread disease, which affects two thirds more women than men (Kourilovitch, Galarza-Maldonado et al. 2014); this is represented in Table 2.1 which demonstrates the prevalence of Rheumatoid Arthritis by gender in Europe and North America (Tobón, Youinou et al. 2010).

TABLE 2. 1 PREVALENCE OF RHEUMATOID ARTHRITIS BY GENDER (TOBÓN, YOUINOU ET AL. 2010)

Country	Females (%)	Males (%)
United States	1.4	0.74
United Kingdom	1.16	0.44
Spain	0.8	0.2
Italy	0.51	0.13
France	0.51	0.09
Greece	0.45	0.19

In 2006 Alamanos et al (2006) conducted a systematic review of incidence and prevalence studies of Rheumatoid Arthritis to determine geographical variation and frequency of the disease over time. They identified 28 studies, nine of which were incidence studies, 17 were prevalence studies and two were both. There were no incidence studies from developing countries. They revealed that there was a significant difference between prevalence of Rheumatoid Arthritis in Northern Europe and North America, compared to the developing countries. Tobin et al (2010) demonstrate this difference in Table 2.2.

TABLE 2. 2 INCIDENCE AND PREVALENCE OF RHEUMATOID ARTHRITIS (TOBÓN, YOUINOU ET AL. 2010)

Populations	Incidence (cases per 100,000 population	Prevalence (cases per 100,000 population
Northern Europe	29 (24 – 36)	0.5 (0.44 – 0.8)
Southern Europe	16.5 (9 – 24)	0.33 (0.31 – 0.5)
North America	38 (31 – 45)	0.5
Developing Countries	No data	0.35 (0.24 – 0.36)

Thus, it is clear that the lack of evidence from developing countries will impact on the understanding of a worldwide view of the incidence and prevalence of Rheumatoid Arthritis. Indeed, the influence of the different health care systems in countries around the world where medical care is limited will further contribute to the underestimation of the incidence and prevalence of this disease.

2.2.3 Causes of Rheumatoid Arthritis

A single cause of Rheumatoid Arthritis is unknown; however, multiple causal factors have been identified which may contribute to the triggering and course of the disease. In 1996 Silman et al (1996) undertook a study comparing twins with Rheumatoid Arthritis and their unaffected co-twin. 79 identical twins and 71 non-identical twins enrolled onto the study. The aim of the study was to determine whether smoking had any effect on the susceptibility to developing Rheumatoid Arthritis. They found that there was a greater incidence of Rheumatoid Arthritis in the twin that smoked cigarettes than the twin that did not. However, a major limitation of this study was that the numbers were very small as the majority of twins both smoked. Further work has since been undertaken investigating the possible link with smoking and the development of Rheumatoid Arthritis. De Hair et al (2013) recruited 55 individuals considered at risk from developing Rheumatoid Arthritis. These individuals all had Rheumatoid Arthritis specific autoantibodies, but did not present any of the clinical features of the disease upon examination. Smoking was assessed as either never or ever smoked. They found that after 13 months, 27% of these individuals developed

arthritis in association with smoking. After 27 months, this increased up to 60% in patients with a smoking history and had a Body Mass Index (BMI) greater than 25. They concluded that smoking and obesity increased the risk of developing Rheumatoid Arthritis, and lifestyle factors should be critically examined with the aim of disease prevention.

The connection between obesity and Rheumatoid Arthritis has been further investigated in recent years. A study by Lu et al (2014) enrolled participants in America into two studies. 109,896 women were enrolled in the Nurses' Health Study and 108,727 women were enrolled in the Nurses' Health Study II. They collected data through questionnaires and categorised body weight into normal (BMI 18 - 25), overweight (BMI 25 - 30) and obese (BMI 30). Lu et al validated a total of 1181 incident cases of Rheumatoid Arthritis and revealed a trend towards an increased risk of developing the disease in those individuals who were overweight and obese. There was a 37% increase in risk in those individuals who had ten cumulative years of being obese. The Swedish Pharmacotherapy Trial (SWEFOT) (Levitsky, Brismar et al. 2017) was a two-year open-label multi-centre randomised early Rheumatoid Arthritis trial where patients were given Methotrexate for three months and then assessed for response to therapy. The data collection for this trial also collected BMI data and it revealed that obesity was associated with worse clinical outcomes. Further, if obesity was present at diagnosis of Rheumatoid Arthritis, it was a strong predictor of non-remission after two years of treatment. Smoking and obesity are modifiable environmental factors; thus, effective health education may have a tangible impact on the progression of this disease in many individuals.

The influence of an individual's genetic make-up has been much studied, and there are some indications that certain genes may make that individual more susceptible to developing the disease (Choy 2012, Korczowska 2014, Levitsky, Brismar et al. 2017). This is a specific area of scientific enquiry and beyond the scope of this thesis. The work around the influence of pathogens, in particular the pathogen causing periodontal infection is of particular interest. Leech and Bartold (2015) express that the relationship between Rheumatoid Arthritis and poor dental health has been recognised for decades and that there is a clear association between periodontitis and the risk of developing Rheumatoid Arthritis. Araujo et al (2015) conducted a literature review of 26 articles and concluded that the majority of the work confirmed the connection between periodontitis and Rheumatoid Arthritis. Kharlimova et

al (2016) further suggest that the link between Rheumatoid Arthritis and periodontitis is the pathogen Porphyromonas gingivalis and conclude that it is a strong candidate for driving autoimmune disease in some patients with Rheumatoid Arthritis. Periodontitis is an inflammatory condition which is a major cause of tooth loss which is preventable by reducing lifestyle factors such as smoking and by sustaining high standard of plaque removal (Chapple, Van der Weijden et al. 2015). Thus, the intervention of early health education could have an impact on the incidence and severity of Rheumatoid Arthritis.

2.2.4 Definition and Clinical Features

Rheumatoid Arthritis is characterised by progressive and irreversible damage to the joint spaces of synovial-lined joints (Grassi, De Angelis et al. 1998). In a normal joint, the joint is surrounded by a fibrous capsule which is lined with synovial membrane. The articular surfaces of the joints are protected by cartilage. Within the capsule, the synovial membrane secretes synovial fluid which further reduces friction on joint movement. The synovial fluid is constantly being absorbed and replaced by the synovial membrane in the joint cavity (Levick and McDonald 1995).

In people with Rheumatoid Arthritis there is an increased production of cells called synoviocytes. In normal joints these cells appear to be responsible for synovial fluid production and reabsorption (Iwanga, Shikichi et al. 2000), however in people with Rheumatoid Arthritis an over-production of these cells leads to the overgrowth of the synovial membrane, which, on appearance, looks like long villous-like folds (Isaacs 2011). This in turn results in a pannus-like structure which extends into the joint space (Bustamante, Garcia-Carbonell et al. 2017) and an increased production of synovial fluid. New blood vessels infiltrate the pannus-like structure which produces molecules and proteins such as cytokines, destroying the cartilage, tendons and bones which form the joint.

The most common joints to be affected in the early stage of the disease are the small joints of the hands and feet, then wrists, ankles, elbows, shoulders and knees, although any synovial joint can be affected (Jeffery 2014). Most people will present with pain and swelling

of their joints, often with morning stiffness in the joints which is caused by a build-up of synovial fluid overnight (Isaacs 2011).

The initial diagnosis can be difficult as there are a number of other causes of these symptoms, Table 2.3 describes some other causes of painful swollen joints.

TABLE 2. 3 CAUSES OF PAINFUL SWOLLEN JOINTS BASED ON ISAACS (2011)

Rheumatoid Arthritis	Osteomalacia
Psoriatic Arthritis	Hyperparathyroidism
Enteropathic Arthritis	Renal Bone Disease
Reactive Arthritis	Lyme Disease
Reiter's Syndrome	Subacute Bacterial Endocarditis
Ankylosing Spondylitis	Multiple Myeloma
Post-viral Arthritis	Septic Arthritis (usually affects one joint)
Inflammatory Osteoarthritis	

A variety of other clinical features are associated with Rheumatoid Arthritis: neuromuscular complications can lead to muscle wasting around affected joints, cervical spine disease which can cause atlanto-axial subluxation and spinal cord depression (Isaacs 2011). Systematic features of Rheumatoid Arthritis can present as nodules commonly seen around the wrists, hands and elbows, lymphadenopathy and amyloidosis. Haematological conditions such as anaemia can occur and lung disease such as interstitial pneumonitis can also be features of Rheumatoid Arthritis. It is therefore essential that early diagnosis of this disease is carried out in order to treat this progressive and potentially destructive condition (Isaacs 2011). In 1987 the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) produced criteria to classify Rheumatoid Arthritis which were updated in 2010 (Van Der Heijde, Van Der Helm-Van et al. 2013), Table 2.4 shows this criteria.

TABLE 2. 4 ACR/EULAR 2010 CLASSIFICATION CRITERIA FOR RHEUMATOID ARTHRITIS

Clinical Finding	Score
Joint Involvement	(0 – 5)
1 large joint	0
2 – 10 large joints	1
1 – 3 small joints (± large joint involvement)	2
4 – 10 small joints (± large joint involvement)	3
> 10 joints (with at least one small joint)	5
Serology	(0 – 3)
Negative Rheumatoid Factor (RF) and negative Anti-Citrullinated Protein Antibodies (ACPA)	0
Low positive RF or low positive ACPA	2
High positive RF or high positive ACPA	3
Acute phase reactants (inflammatory markers)	(0 – 1)
Normal C-reactive Protein (CRP) and normal Erythrocyte Sedimentation Rate (ESR)	0
Abnormal CRP or abnormal ESR	1
Duration of Symptoms (patient reported symptoms)	(0 – 1)
< 6 weeks	0
> 6 weeks	1

The aim of the criteria was to classify and diagnose Rheumatoid Arthritis early in the disease, and those patients who fit the criteria were then highly likely to develop the disease. However, some individuals who did not fit the criteria for Rheumatoid Arthritis would still go on to develop it (van der Helm-van and Huizinga 2012).

In order to apply the above criteria, there must be at least one swollen joint present with no other explanation for this and the patient must score at least six points. Early detection of

the disease is essential to reduce or halt joint damage (Smolen, Aletaha et al. 2007). Smolen et al also comment that people with Rheumatoid Arthritis not only have pain and swelling, they also have loss of physical function which can be due to inflammation or joint damage. Inflammation can be reversible but joint damage cannot and damage will increasingly progress without treatment. In 1957 Duthie et al (1957) published a report on the course and progress of Rheumatoid Arthritis, it makes interesting reading and illustrates the prognosis of Rheumatoid Arthritis at that time. Duthie et al carried out three assessments on a cohort of 307 patients with Rheumatoid Arthritis between June 1948 and July 1951. Table 2.5 shows the composition of the patient cohort over the three assessments.

TABLE 2. 5 COMPOSITION OF COHORT OF PATIENTS OVER THREE ASSESSMENT (DUTHIE, BROWN ET AL. 1957)

Data	Total
Mean duration of stay in hospital (weeks)	9.4
Average period between discharge and first assessment (months)	24.4
Number of deaths between discharge and first assessment	15
Number of participants left at first assessment including those no longer available	282
Average period between discharge and second assessment (months)	52.4
Number of deaths between discharge and second assessment	26
Number of participants left at second assessment including those no longer available	258
Average period between discharge and third assessment (months)	67.4
Number of deaths between discharge and second assessment	36
Number of participants left at third assessment including those no longer available	247

After only three years following discharge, 36 people with Rheumatoid Arthritis had died and a further 24 were lost to follow up. Six of those individuals who had died were under the age of 50 years and 21 were between 50 and 70 years. Functional capacity was assessed as a grade, described in Table 2.6.

TABLE 2. 6 GRADES OF FUNCTIONAL CAPACITY (DUTHIE, BROWN ET AL. 1957)

Grade	Definition	Remarks
I	Fit for all normal activities	Full employment in usual work, full house duties
II	Moderate restriction	Usual employment with modifications Light or part-time work All housework except the heaviest No dependency on others
III	Marked restriction	Only very light work or light house work Some degree of dependency on others
IV	Confined to chair or bed	Not capable of any work Completely dependent on others

Table 2.7 shows the functional capacity of the participants at the three assessments and illustrates the progressive nature of Rheumatoid Arthritis at a time when treatment for this disease was limited, and the progress and impact of treatment will be discussed later in this Chapter (section 2.3).

TABLE 2. 7 FUNCTIONAL CAPACITY OF STUDY PARTICIPANTS (DUTHIE, BROWN ET AL. 1957)

Timepoint	Functional Grades (%)					
	I	II	III	IV	I+II	III+IV
Admission	___	35.4	42.6	22.0	35.4	64.6
Discharge	11.3	64.2	24.1	0.4	75.5	24.5
First Assessment	28.4	44.0	25.1	2.5	72.4	27.6
Third Assessment	23.5	40.4	26.7	9.3	64.0	36.0

The significance of this report and the reason for including it in this review, is that it illustrates that patients who had Rheumatoid Arthritis were very ill and debilitated by their disease, requiring hospital admission and treatment. However, the treatment that these patients received in the 1950s consisted of bed rest, the application of plaster splints to try to prevent deformities of the joints and the maximum dose of aspirin that the patient could tolerate. Whilst, with this care, the patients appeared to regain some functionality during their hospital admission, their disease slowly progressed over the three years they were assessed, with just over one third of patients being classified as requiring some or a lot of help from others. It highlights that Rheumatoid Arthritis was a very debilitating and progressive disease, sometimes requiring lengthy stays in hospital undergoing conservative treatment. Today, the prognosis for people with Rheumatoid Arthritis is a lot brighter, because the treatment regimens for this disease have progressed enormously, and will be discussed later in this chapter. However, it still has an impact on people's daily lives and it is important to remember that individual sufferers need to understand why their treatment is so important and the advantages of taking it as prescribed.

2.2.5 Impact on Daily Living

Much has been written about the impact of Rheumatoid Arthritis on the lives of those people who suffer from this disease. Lempp et al (2006) conducted a qualitative study with 26 individuals living with Rheumatoid Arthritis. They wanted to understand the direct and

personal experiences of these people who lived with Rheumatoid Arthritis on a daily basis to gain further understanding of the impact this disease had on the lives of these patients. For example, their ability to care for others, their public roles and responsibilities and their self-image. Semi-structured interviews were conducted with these patients and several themes were identified, including the impact of their disease on their mental health, loss of independence and feelings of stigmatization which related to deformities of their hands or because they needed to use a stick or a scooter. Whilst Lempp et al recognise that the findings of their study are not generalisable, they revealed details of patients' daily lives which may not have been captured by questionnaires. However, questionnaire studies have disclosed that quality of life can be affected by Rheumatoid Arthritis (Haroon, Aggarwal et al. 2007). Haroon et al investigated the quality of life of patients with Rheumatoid Arthritis using a short form of a questionnaire designed by the World Health Organisation called the World Health Organisation Quality of Life Scale (WHOQOL-BREF), which is a shorter form of the original WHOQOL-100 (Power, Bullinger et al. 1999). The long form of the questionnaire consists of 100 items divided into four domains; physical capacity (including independence), psychological (including spirituality), social relationships and environment. The short form consists of 26 items based on the same domains which is far easier to administer during a clinic. One hundred and thirty-six patients completed the WHOQOL-BREF and all patients had Rheumatoid Arthritis. The study revealed that physical health was the domain that most patients felt affected their quality of life the most. However, a limitation of the study was that it did not assess depression and anxiety, which are important considerations that are discussed in the following section.

2.2.6 Depression

Rheumatoid Arthritis is a disease which has a debilitating impact on the lives of the sufferers; it not only has a physical impact, as outlined in the previous sections, but a psychological impact also. It has long been known that people with Rheumatoid Arthritis can also suffer from depression or have depressive symptoms (Frank, Beck et al. 1988). Matcham et al (2013) conducted a systematic review in order to describe the prevalence of depression in people with Rheumatoid Arthritis. They highlighted that the prevalence

estimates of depression in patients with Rheumatoid Arthritis was widely variable and ranged between 9.5% and 41.5%. However, they regarded that the identifying depression was not straightforward. There are a number of different methods for collecting data on depression from patients, but these can be very time consuming. Therefore, self-report questionnaires such as the Patient Health Questionnaire (PHQ) and the Hospital Anxiety and Depression Scale (HADS) are often utilized because they can collect a large amount of data from a bigger population of subjects. Other confounders could be study quality and sampling strategies which could influence prevalence estimates. Matcham et al (2013) concluded that depression was defined in 40 different ways and three subtypes; major depressive disorder, minor depressive disorder and dysthymic disorder, a chronic depressive disorder. Only seven studies used the longer psychiatric assessment tools, the remaining 66 used the shorter diagnostic tools, and 30 studies used the HADS, making it the commonest questionnaire used. On examination of the seven studies which used the longer assessment tools, it was suggested that 16.8% of patients with Rheumatoid Arthritis could have major depressive symptoms. Whilst the remaining 66 studies used the shorter assessment tools, the PHQ and the HAD, the evidence suggests that between 14.8% and 48% of the population under study had significant depressive illness (Hughes 2010). Rezaei et al (2014) assessed 100 patients with Rheumatoid Arthritis, who completed four questionnaires; including the Rheumatoid Arthritis Pain Scale (RAPS) and the HADS. The findings revealed that 66% of the patients had a clinically significant level of depression. Rezaei et al concluded that a negative perception of uncontrollable pain was associated with a higher level of symptoms of depression in this group of patients. They postulated that this could be mediated through a perceived lack of personal control over their illness, functional impairment and possible poor medication compliance due to their depressive symptoms. Thus, it is possible that engaging the patient at the beginning of their treatment, ensuring that they have a clear understanding of why they are taking drugs like Methotrexate, which could lead to improved compliance, may have an impact on depressive symptoms.

2.2.7 Fatigue

Fatigue is commonly reported by patients with Rheumatoid Arthritis, and has been the focus of study for some time (Wolfe, Hawley et al. 1996). Wolfe et al measured fatigue on a visual analogue scale on 1488 consecutive patients with Rheumatic disease and found that significant levels of fatigue were present in around 41% of patients with Rheumatoid Arthritis. An early qualitative study by Hewlett et al (2005) considered that fatigue is multi-dimensional, the consequences of which can have an impact on every aspect of daily life. Interviews with 15 patients with Rheumatoid Arthritis and fatigue, who had rated seven on a visual analogue scale, zero being no fatigue and ten being the worst fatigue, identified that the patients experienced two different types of fatigue; severe weariness and dramatic overwhelming fatigue, which had far reaching effects of every aspect of their lives. The patients also reported that they did not discuss fatigue with their clinicians which highlights the importance of good consultation to draw out these symptoms. One of the limitations of this study is that the patients they interviewed had gross fatigue symptoms to begin with and this may not necessarily be representative of the general Rheumatoid Arthritis population. Therefore, this study does lack generalisability. Nevertheless, it does highlight that fatigue can be a very real and debilitating symptom of Rheumatoid Arthritis which was not necessarily recognised in the Rheumatology speciality at that time. The measurement of fatigue was also not an important outcome measure in clinical trials either (Hewlett, Cockshott et al. 2005). Hewlett et al interviewed 15 patients with Rheumatoid Arthritis and fatigue and concluded that validated assessment tools to measure fatigue in people with Rheumatoid Arthritis, could yield more robust evidence on the existence and extent of fatigue and indeed, determine whether levels of fatigue changed due to participation in a clinical trial.

The OMERACT group (Outcome Measures in Rheumatology Clinical Trials) was convened in 1992 as an international initiative to improve outcome measurements in Rheumatology (Tugwell, Boers et al. 2007) and consisted of 80 participants including 20 patients from ten countries, and they measured the impact of fatigue on patients. This provided a turning point in highlighting to healthcare professionals the impact of fatigue on patients with Rheumatoid Arthritis (Choy and Dures 2019). As a result of this, Choy and Dures point out that more researchers have focussed on understanding the underlying causes of fatigue in

Rheumatoid Arthritis and thus contributed to the management of these patients. But the overarching challenge is that the fundamental causes of fatigue remain unclear. Choy and Dures suggested that the current evidence points to a complex interaction of clinical factors, such as pain, inflammation and immobility, psychosocial factors such as coping factors, mood beliefs and behaviours, and personal factors such as work, caring responsibilities and comorbidities. Katz (2017) carried out a review of current understanding on fatigue in Rheumatoid Arthritis and reviewed existing treatment. Katz reported that drugs used to treat Rheumatoid Arthritis had limited effect, but physical activity interventions showed a moderate, but significant impact on fatigue. Further Katz conveyed that psychosocial interventions have also resulted in moderate but significant effects. It is clear that fatigue in Rheumatoid Arthritis is a significant burden to the sufferer, however, research continues and a richer understanding of the causes and treatment of fatigue will eventually lead to enhanced disease management for people with Rheumatoid Arthritis.

2.2.8 Work Disability

Rheumatoid Arthritis can also have an impact on employment. Verstappen et al (2004) carried out a literature review of 27 cross-sectional and longitudinal studies that examined risk factors associated with work disability amongst people with Rheumatoid Arthritis. On analysis of the longitudinal studies, work disability was found to increase with duration of disease from 10% in the first year of disease to 90% at 30 years of duration of disease. Among the cross-sectional studies, work disability varied from 13% after six months disease duration to 67% after a mean disease duration of 15 years. They also highlighted a number of variables associated with work disability, the most frequently presenting were socioeconomic factors, clinical variables and work-related reasons. Socioeconomic factors often related to age, those patients who were older were more likely to stop work due to their symptoms of Rheumatoid Arthritis. They also found that those patients who were less well educated and had low incomes were more likely to stop work due to their Rheumatoid Arthritis. The clinical variables related to symptoms, those patients who were work disabled had higher levels of inflammation, higher pain scores and higher disease activity. The work-related factors which led to work cessation, included the population who were in more

physically and emotionally demanding jobs. Whilst it seems apparent that Rheumatoid Arthritis can lead to a loss of work productivity and employment, this study did not describe the assessment tools used to measure work disability. It is clear that being able to work and function at work is an important outcome for people with Rheumatoid Arthritis, and standardised measurement tools are required in order to understand and manage these factors.

In a study of patient derived targets for treatment, Robinson et al, (2011) carried out a survey of 100 patients with Rheumatoid Arthritis. They negotiated a target for treatment with each patient, so that if, when the patient was reviewed after three to six months, the target was achieved, then it would be considered that treatment was successful. If the target was not achieved, then it may be considered that the patient required a further change or escalation of treatment. The target was chosen by the patient in consultation with the researcher. There were 44 patients who fell into the working age population (men <66 years and women <60 years) and 40% of these were in paid employment (n=21), whilst the rest of that population had stopped work. Twelve of those patients who were in paid employment chose as their target, to remain in work, one patient chose the target of increasing their current paid employment. None of the working age population, who were not in work, chose regaining employment as their target. This study suggested, that once work is lost, then it was no longer a target for them to get back to work. It is therefore likely that preventing work loss would be the better strategy. Thus, it is important that patients have the knowledge to understand that taking drugs like Methotrexate as prescribed could have a positive impact on maintaining their employment.

2.3 Treatment of Rheumatoid Arthritis

The next few sections will review the historical treatment of Rheumatoid Arthritis, the development of the disease modifying drugs used to treat Rheumatoid Arthritis with particular reference to Methotrexate, as it is the focus of this study. There will also be a brief discussion of the biologic drugs which are used to treat this disease, as many of them require Methotrexate to be prescribed in combination with their use.

2.3.1 Historical Treatment

The treatment of Rheumatoid Arthritis before the 1950s was bleak for people who suffered from this painful and debilitating disease. Patients resorted to remedies with no scientific basis that were at best harmless, to relieve their suffering, such as suspending a copper coin on a gut string and tying it around the waist. Today people still wear copper bracelets in the hope that they will ward off and control arthritis symptoms. Other remedies involved fluids and salts of different sorts taken by mouth, special herbs, diets and baths. Bloodletting and leeching were popular in the distant past, but even in the 1970s cupping, acupuncture, wax baths were common forms of treatment.

The only effective disease modifying agent was Myocrisin, a gold salt (sodium aurothiomalate) (Ellman, Lawrence et al. 1940, Sutcliffe, O'brien et al. 1973). In the late 18th Century gold cyanide was being developed intravenously for the treatment of Tuberculosis. After initial encouraging reports, experimental use in other conditions occurred. In the 1920s favourable results were seen with gold salts given intramuscularly in the treatment of Rheumatoid Arthritis and its use for this condition spread rapidly around Europe (Fraser 1945, Sigler, Bluhm et al. 1974). The 1930s saw the first use of gold in the UK as a therapy for the treatment of Rheumatoid Arthritis. It was used as a last line of drug treatment because of the risks of side effects; patients would be expected to have signs of permanent damage such as erosion to justify its use. Instead, analgesia and non-steroidal anti-inflammatories were used as first line drugs to treat Rheumatoid Arthritis. Gold injections continued to be prescribed for the treatment of Rheumatoid Arthritis until 2019 when it was withdrawn worldwide as no company could manufacture it because of supply problems with the ingredients (Sanofi 2019).

A real breakthrough for the treatment of chronic long-term conditions like Rheumatoid Arthritis was the discovery of cortisone, Compound E, by Philip Hench in 1948, for which he won the Nobel Prize for Physiology or Medicine in 1950 (Burns 2016) along with his co-workers Edward Kendall and Tadeus Reichtein. Compound E was rated to be of equal importance to the discovery of insulin and penicillin; the effect of Compound E, “is almost beyond comprehension, the time is not far distant for Rheumatoid Arthritis to be wiped out” (Karsh and Hetenyi Jr 1997). At that time the mode of action of Compound E was unknown,

but from the onset the major confounder in the widespread use of this drug was its availability; it was extremely scarce, difficult and costly to produce. A series of Parliamentary debates between 1949 and 1954 around the availability of Cortisone (see Appendix 1), reflected on the increased recognition of side effects associated with hydrocortisone usage which are associated with long-term use, including osteoporosis, diabetes, cataracts, infections and mood changes. It was therefore recognised that corticosteroids such as hydrocortisone could not be used in high doses over long periods, and they are now mainly used for short term "boosts" to other therapies.

Aspirin was first synthesized in 1897 and marketed as an anti-inflammatory drug, but its mode of action remained elusive until 1971 when John Vane showed that aspirin and other similar drugs such as indomethacin, inhibited the production of prostaglandins which produced an anti-inflammatory effect. However, prolonged use of these drugs caused damage to the stomach mucosa, toxicity to the kidneys and inhibition of platelet aggregation (Botting 2010). Other NSAIDs have since been developed which are less harmful to the stomach mucosa such as the COX-2 inhibitors (Brune and Hinz 2004). NSAIDs are still important drugs in the treatment of Rheumatoid Arthritis but their limitation is that they only act on the symptoms of the disease and not the disease process itself. In 2018 the National Institute of Health and Care Excellence (NICE) updated their guidelines on the management of patients with Rheumatoid Arthritis. They recommended that NSAIDs should be used to treat inadequate control of pain and stiffness at the lowest possible dose for the shortest possible time (Allen, Carville et al. 2018).

2.3.2 Development of DMARDs

Gold was in retrospect the first drug thought to slow the progression of Rheumatoid Arthritis. Drugs that do this are now called Disease Modifying Anti Rheumatic Drugs (DMARDs). The next drug in this group was Sulphasalazine, introduced in the late 1970s. Sulphasalazine was developed in Stockholm by Professor Nana Svartz (1948) but it remained unused because of the introduction of cortisone in the 1950s. However, studies carried out in the late 1970s awakened interest in this drug (McConkey, Amos et al. 1980). In the 1950s

a drug called Penicillamine was found to be anecdotally effective in the treatment of Rheumatoid Arthritis and a meta-analysis of studies showed it to have a statistically significant benefit on disease activity (Suarez-Almazor, Belseck et al. 2000) It was thought that it could useful in the management of patients who had stopped or failed to respond to gold injections (Tsang, Patterson et al. 1977). However, it has declined in use with the development of other more effective DMARDs.

Hydroxychloroquine is a drug which was principally prescribed to treat malaria, however since the 1950's studies showed that it was useful in the treatment of Rheumatoid Arthritis (Ryan 2007). Hydroxychloroquine has a low toxicity profile but it tends to be used in combination with other drugs as it is slightly less effective than other DMARDs (Ryan 2007). Cyclophosphamide is a drug that was developed for the treatment of cancer and it was shown to have immunosuppressant and immunostimulatory effects (Miller and North 1981). It found some use in the treatment of Rheumatoid Arthritis in the 1960's, but it proved to be more effective in the treatment of some of the systemic effects of this disease (Ryan 2007).

2.3.3 Methotrexate

Methotrexate is a compound that was first used to treat Rheumatoid Arthritis in 1951 (Gubner, August et al. 1951). Unfortunately it emerged at the same time as cortisone, thus receiving little attention until it came back into focus in the early 1980's (Hoffmeister 1983). Methotrexate, which is a folate antagonist, was developed in the late 1940's after the discovery that a dietary deficiency of folic acid resulted in a decrease in leukaemia cell count (Heinle and Welch 1948). Further investigation with Methotrexate found it had a role in many different types of cancer, though it was more effective when used with other cytotoxic drugs (Bryan 2019). Methotrexate found use in the treatment of Psoriasis (Coe and Bull 1968) but the observed liver toxicity meant that routine liver biopsies were performed. However, the pick-up rate was low and they have since been discontinued as a routine treatment (Boffa, Chalmers et al. 1995).

In 1972 Hoffmeister (1972), carried out an observational clinical study on 29 patients who had Rheumatoid Arthritis and prescribed them intramuscular Methotrexate. He reported

that 11 of his patients had a major improvement of the symptom and signs of their disease, and 14 had moderate improvement. When he discontinued the Methotrexate 80% of these patients had major flares. This report was only published as an abstract because his Rheumatology colleagues responded so negatively, he did not want to waste time on a manuscript, which would be rejected (Weinblatt 2013). In 1983 Weinblatt (1985) initiated a randomised, placebo-controlled, 24-week crossover trial of 28 patients with Rheumatoid Arthritis in which 2.5mg to 5mg twice a day was prescribed three days per week. The Methotrexate group showed a significant improvement in both tenderness and swelling of the joints, by week 12. However, side effects were noted; 12% reported diarrhoea and one patient was withdrawn due to severe diarrhoea, and 21% of the Methotrexate group exhibited raised liver enzymes. They concluded that Methotrexate was effective in the short term but longer trials were required, so 26 patients agreed to continue taking Methotrexate (Weinblatt, Trentham et al. 1988). Ten patients withdrew from this long-term study, so at month 36, only 16 patients were still taking Methotrexate. Adverse events such as nausea, headache, increased infections, diarrhoea, raised liver enzymes and neutropenia were noted. However, these adverse events resolved after short term withdrawal of Methotrexate. Further, the disease remained well controlled in the remaining patients and radiographic joint damage showed improvement. Weinblatt et al concluded that drug toxicity could be managed with regular monitoring of the patient, thus confirming Methotrexate an effective drug for the treatment of Rheumatoid Arthritis.

A further pivotal study conducted in the mid 1980”s was developed by Williams et al (1985). One hundred and ten patients completed an 18-week placebo-controlled randomised trial. All patients were naïve to Methotrexate and all patients had six or more swollen joints on entry into the study. Fifty-seven patients were randomly allocated to the Methotrexate group and 53 into the placebo group. The starting dose for the Methotrexate group was 7.5mg per week; 33% of patients remained on this dose, whilst the rest stepped up to 15mg per week. Joint pain and tenderness in the Methotrexate group had decreased by more than 50% at the end of week 18 and only by 11% in the placebo-controlled group. There were also significant improvements in the duration of morning stiffness, grip strength and walking time in the Methotrexate group.

However, despite the evidence from these studies, Methotrexate was used very slowly initially and usually as a last resort treatment for patients with severe disease. But during the 1990s further long-term data from studies reported sustained clinical response, which increased the interest of Rheumatologists worldwide and Methotrexate became more universally used as a monotherapy and in combination with other drugs. Williams et al (1992) entered 335 patients into a 48 week prospective, controlled double-blind trial and were randomly assigned to one of three groups:

- Methotrexate monotherapy – 7.5 mg weekly
- Auranofin monotherapy 3mg twice a day
- Combination of Methotrexate and Auranofin 7.5 mg weekly and 3mg twice a day respectively

All patients had active Rheumatoid Arthritis with at least six swollen joints and all patients were monitored every three weeks for adverse events. Whilst a similar trend of the reduction of the number of tender joints was seen across all three groups, patients responded to Methotrexate more quickly, but by week 18 all groups were comparable. Of the 124 patients who were withdrawn, it was more frequent in the combination group (21%) compared to 14% in the Auranofin group and 15% in the Methotrexate group. Twenty-five patients were withdrawn because of lack of efficacy and of these 13% belonged to the Auranofin group. The total withdrawal of patients for any cause over the entire study were 40% in the Auranofin group, 34% in the Methotrexate group and 37% of patients in the combination group. Increase liver enzymes were only seen in the Methotrexate group and was the most common cause of withdrawal. No increase in efficacy was seen in the combination group, but withdrawals because of lack of response was more common in the Auranofin group.

Despite the increasing amount of evidence from clinical trials, Rheumatologists were still initially reluctant to use Methotrexate during the 1990's, which could have been for three reasons (Pincus, Yazici et al. 2003); that Rheumatologists were more comfortable using the established DMARDs, that they perceived that more potent drugs were more toxic and that they were concerned about possible irreversible harmful effects.

2.3.3.1 Methotrexate Side Effects and Toxicity

The side effects of Methotrexate can be diverse and life threatening (Gaies, Jebabli et al. 2012). As Methotrexate was initially used to treat cancer and was administered in doses much higher than used in the treatment of Rheumatoid Arthritis, there was initially very limited information on common side effects. Also the drug was not formally licenced for Rheumatoid Arthritis until a subcutaneous injection was studied (Mims 2006) and most of the early information came from case studies (Steinsson, Weinstein et al. 1982). Methotrexate had not, therefore, been subjected to large phase III studies that would satisfy regulators and thus confidence to use it was gained mainly from experience. Weinblatt and colleagues (1985) report the toxicity in 587 trial patients reporting effects on the gastro-intestinal tract, the bone marrow, alopecia and fever. A cross-sectional observation study point was conducted by Gilani and colleagues (2012) on patient who were receiving a low dose of Methotrexate. They showed that 27% of the study population (n=140) suffered side effects. These were mostly hepatological and haematological, with the commonest problem being raised liver enzymes. But the main draw back with this study was that they only examined blood samples, whilst the patients themselves were not asked about the side effects they encountered taking Methotrexate.

Tolerability of Methotrexate is a problem for many patients, van Ede et al (1998) found that 30% of patients starting Methotrexate stopped because of side effects (van Ede, Laan et al. 1998), making it clear that drug and dose limiting side effects are frequent and have a significant impact on adherence. Similarly, Alarcon, Tracy and Blackburn (1989) surveyed 152 patients over five years and found that 71.2% were self-reporting that they were still taking Methotrexate at one year, 55.5% at three years and only 50% at five years. However, the data were collected from patient notes, rather than surveying the patients themselves, which may not consider the number of patients who do have side effects but do not report them. Robinson et al (2016) carried out a survey of patients taking Methotrexate in seven centres around the UK. The total number of patients who experienced side effects ranged from 57% in one centre to 85% in another centre. The patients were asked to complete visual analogue scales to score the severity of side effects they experienced. Fatigue scored the highest, whereas mouth ulcers and hair loss were scored much lower. This study reported a high frequency of side effects endured by patients, which could indicate that

patients are tolerating Methotrexate because of the benefit they receive from it. It was also revealed through this survey, that patients occasionally take a "Methotrexate holiday", ie they will miss out doses if they go on holiday or if they intend to consume alcohol at a party. Whilst it is possible that patients manage their Methotrexate in order to suit their needs, there are dramatic and life-threatening side effects of Methotrexate. Pneumonitis is inflammation of the lining of the lungs and fibrosis, where the lungs can become damaged and scarred, can occur as a result of taking Methotrexate (Carson, Cannon et al. 1987). Guidelines produced by the British Society of Rheumatology advise using caution when using drugs such as Methotrexate in patients with poor respiratory reserve and therefore investigation of the lungs is now routine prior to commencing Methotrexate therapy (Ledingham, Gullick et al. 2017). There is a suggestion that there may be genetic factors which predispose the patient to increased risk of toxicity (Fisher and Cronstein 2009), but this has not found a clinical position at this time.

Lloyd et al (1999) published a review in which they highlighted that a number of studies had shown that there was a link between Methotrexate and birth defects. Feldcamp (1993) suggested that the lowest dose which would produce adverse effects on pregnancy was 10mg, the most vulnerable period of gestation being between six to eight weeks. Lloyd et al (1999) reported that skull and limb abnormalities were the most common effects of Methotrexate exposure and there was a 10:42 chance of abnormalities of the foetus in the event of exposure to the drug, thus it was recommended that Methotrexate should be withdrawn six months prior to pregnancy. However, as drug treatment during pregnancy may be required to control maternal symptoms a EULAR task force was established to conduct a systematic literature review and to formulate recommendations for the use of anti-rheumatic drugs during pregnancy (Skorpen, Hoeltzenbein et al. 2016). Whilst many drugs used to treat Rheumatoid Arthritis could be continued with caution, Methotrexate was one of the drugs which they advised should continue to be withdrawn before pregnancy. Therefore, females and males of childbearing age who are taking Methotrexate should be clearly aware that this drug should be withdrawn prior to any planned pregnancy.

A further complication of the use of Methotrexate is the link with liver cirrhosis. In 1977 liver biopsies were carried out on 160 patients who were all taking Methotrexate up to a maximum dose of 25mg (Nyfors 1977) discovered that 26% had liver cirrhosis. Further

studies were carried out, leading to guidelines for hepatic monitoring (Kremer, Alarcón et al. 1994). The association between alcohol and liver was known (Savolainen, Liesto et al. 1993) therefore the guidelines published by the American College of Rheumatology recommended complete abstinence (Kremer, Alarcón et al. 1994). However, somewhat more recently, the British Society of Rheumatology suggested that alcohol consumption should be limited to "within the UK national recommendations" (Chakravarty, McDonald et al. 2008). Humphreys et al (2017) felt that there was a lack of evidence to reveal the toxic effects of alcohol and Methotrexate combined, thus they identified 11839 patients with Rheumatoid Arthritis from an electronic database of routinely collected medical records in primary care of patients starting Methotrexate after 1987. Humphreys et al identified episodes of raised liver enzymes, alanine transaminase (ALT) or aspartate aminotransferase (AST), which were greater than three times above the upper limit of normal, which could indicate liver toxicity, and predispose liver cirrhosis. They found that most patients drank low amounts of alcohol – less than seven units per week or did not drink at all. They also demonstrated that there was not a significant risk of liver toxicity in those patients who drank less than fourteen units per week and concluded that it was relatively safe for patients taking Methotrexate to consume alcohol in line with the UK guidelines. However, correspondence from Kremer et al (2018) in response to Humphreys et al (2017) dispute their findings as they consider that the elevation of the AST and ALT to be greater than three times the upper limit of normal as a measure of the potential for liver cirrhosis as being very misleading. In their work, they consider that liver biopsies were a far better measure of hepatic toxicity and measuring the ALT and AST alone could seriously underestimate the risk for patients. It is clear from this work, that there is a risk of increased hepatic toxicity with the consumption of alcohol whilst on Methotrexate and this is an important message to patients who are taking this drug.

There are relatively few drug interactions with Methotrexate; Bourre-Tessier and Haraoui (2010) conducted a systematic review to determine what drugs could increase side effects or toxicity of Methotrexate and concluded that Methotrexate has limited drug interactions. However, two drugs stood out, Trimethoprim (TMP), which is an antibiotic commonly used to treat urinary tract infections, and high doses of Aspirin (ASA). TMP inhibits an enzyme call dihydrofolate reductase, this has an important role in the building of DNA. However, inhibiting this enzyme can lead to bone marrow suppression. Methotrexate also inhibits

dihydrofolate reductase, therefore a combination of both can lead to serious bone marrow toxicity (Rushworth, Mathews et al. 2015). Bourre-Tessier and Haraoui (2010) also report that there is some evidence to suggest that a combination of Aspirin and Methotrexate could produce drug reactions, however, small doses of Aspirin did not reveal any significant signals for toxicity. The increase in the number of available Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) over the years have negated the need to use high doses of Aspirin and Bourre-Tessier and Haraoui did not observe any significant drug reactions with these NSAIDs.

Vaccinations are an area of concern for patients who are taking immuno-suppressant therapies such as Methotrexate, because live-attenuated vaccines contain live micro-organisms which can cause infection in an immuno-suppressed person (Furer, Rondaan et al. 2020). As a result, the European League Against Rheumatism (EULAR) provided recommendations for the use of vaccines in patients with autoimmune inflammatory diseases such as Rheumatoid Arthritis, firstly in 2011 (Van Assen, Agmon-Levin et al. 2011) and further updated in 2019 (Furer, Rondaan et al. 2020). Generally, non-live vaccines such as the flu vaccine and pneumococcal vaccine are recommended yearly, however EULAR still recommend that live vaccines should be avoided during immunosuppression with a possible exception of the MMR vaccine for children and the Herpes Zoster vaccine. The yellow fever vaccination particularly, should generally be avoided. Thus, it is clear that patients require information which would direct them to resources which would give advice about vaccinations and which ones were safe to receive.

A survey of Rheumatologists carried out in 1992 indicated that Sulphasalazine was the drug of choice for Rheumatoid Arthritis (Kay and Pullar 1992) but by 2004 46.5% of Rheumatologists in the UK were choosing Methotrexate as their first choice of drug (Jobanputra, Wilson et al. 2004). In 2002 the results of an observation study were published (Aletaha and Smolen 2002) which underscored the importance of Methotrexate dosing. Aletaha and Smolen analysed and recorded the DMARD history of 593 patients with Rheumatoid Arthritis from clinics carried out in 1999. They looked at the effect of drug dose on duration of treatment and they found that 59% of patients taking low dose Methotrexate (10mg/week) discontinued the drug whilst only 36% of patients taking doses of 12.5mg stopped treatment and they also revealed that patients on the higher doses remained on Methotrexate significantly longer than the lower doses. They also observed there was a

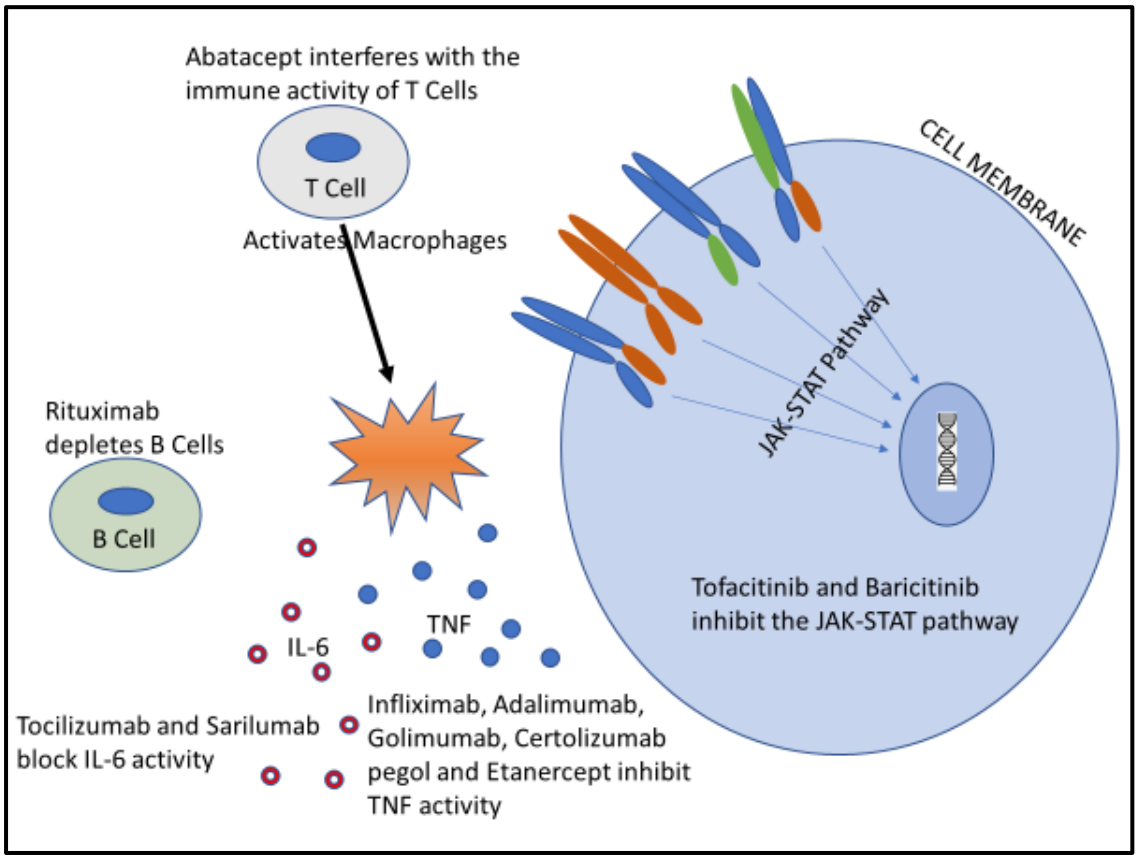
higher toxicity rate in the lower dose group which led to withdrawal rather than lack of efficacy. This was an important finding, because it revealed that once patients were established on higher doses of Methotrexate they were well tolerated and less likely to discontinue treatment. Due to its clinical effectiveness, Methotrexate became the drug of choice for the early treatment of Rheumatoid Arthritis (Albrecht and Muller-Ladner 2010).

Whilst other drugs such as Leflunomide and Sulphasalazine, have been approved with evidence of effectiveness, (Olsen, Strand et al. 1999), the most widely used drug in the UK is Methotrexate and thus is the focus of this thesis. There are many potential side effects of the drug therapies and could have serious consequences for patients and those giving the information, such as the Rheumatology Specialist nurses, as well as those receiving it, the patients, need to understand those risks.

2.3.4 Introduction of Biologics for the Treatment of Rheumatoid Arthritis

Improvements in the understanding of the pathogenesis of RA led to the development of a new class of drugs. These drugs, referred to as biologics, are agents made by living cell lines and target specific inflammatory cells, cell interactions and cytokines which medicate Rheumatoid Arthritis related tissue damage (Curtis and Singh 2011). They are large proteins, either antibodies or receptors, directed against specific mediators of inflammation. The first biologic drugs were developed in the late 1990s (Hsia, Ruley et al. 2006, Amgen 2008), since then other drugs have become available that are often prescribed with Methotrexate (Choy, Freemantle et al. 2019, Genovese, Kalunian et al. 2019). Fig 2.1 shows the site of action for the more commonly used biologic drugs for Rheumatoid Arthritis.

FIGURE 2.1 SITE OF ACTION OF BIOLOGICAL DRUGS FOR RHEUMATOID ARTHRITIS



2.3.5 Current Practice for Managing Rheumatoid Arthritis

The previous section has discussed the evolution of drug therapies for the treatment of Rheumatoid Arthritis with an emphasis on Methotrexate. It shows that there are a wide range of drugs now available to patients for the treatment of their disease. The next section will now discuss the literature on how those drugs are applied to the management of patient with Rheumatoid Arthritis which has changed considerably over the last 30 years. In the 1980s, few drugs with any real therapeutic effect existed, and those that were available were started late in the disease, when the joints were irreversibly damaged (Smolen, Landewé et al. 2017). Therapeutic targets had not been defined, as it seemed that controlling the pain was the most important objective. To date, there are now numerous effective agents to treat Rheumatoid Arthritis and Methotrexate has become the anchor drug for therapy (Visser and van der Heijde 2009, Smolen, Breedveld et al. 2016). Methotrexate is likely to be a mainstay of treatment for many years to come, primarily based

on price. As Methotrexate is off Patent and relatively cheap compared to the biologic alternatives, these more modern and effective drugs will remain less cost/effective for the foreseeable future (Schipper et al 2011). The direction of travel is to treat earlier with quicker escalation of drugs, often used in combination, and treating to a target of remission or low disease activity, ie treat to target. Use of the newer drugs has been restricted by cost, but more recently prices have fallen with the drugs going off patent and "biosimilars" replacing the more expensive originators (Gulacsi, Brodszky et al. 2015). A biosimilar is defined by the World Health Organisation as:

> "a biotherapeutic product that is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product" (WHO 2009).

As originator drugs come off patent, other drug companies can start producing their own version of the drug, biosimilars. These drugs are cheaper than the originators as they do not require the extensive drugs trials required by originator drugs and are therefore cheaper to produce. It has been estimated that Germany, France and the UK could save between €2.3 billion and €11.7 billion between 2007 and 2020 with the introduction of biosimilars for the treatment of Rheumatoid Arthritis (Haustein, de Millas et al. 2012). Thus, whilst it is clear that there have been substantial changes in both the drugs and the way they are used for the treatment of Rheumatoid Arthritis, the impact of treat to target on disease management and the extent to which the patients themselves are involved in this process through shared decision-making needs to be explored.

Schoels et al. (2010) reviewed evidence around the existence of a target-oriented approach the Rheumatoid Arthritis management. They reviewed 24 trials and four trials randomised patients to routine or targeted treatment, two compared different randomised targets and one compared targeted treatment to historical control. The targets for treatment in most of these trials were lowered Disease Activity Score (DAS28), lowered C-Reactive Protein (CRP a protein which can be detected in the blood and measures levels of inflammation) or reduced joint tenderness and swelling. None of the aims of treatment were negotiated between the Clinician and patient. The only reference to patient involvement is a Health Assessment Questionnaire (HAQ), completed by the patient and asks a series of questions of activities of daily living.

Kjeken et al (2006) examined the level of information received by patients, how involved they were with medical care and how satisfied they were with their care. A total of 1,193 patients with RA and Ankylosing Spondylitis (AS) completed self-reported health status questionnaires and questions about Rheumatology care. Questions regarding information received, involvement with decisions and satisfaction with care were also asked. The majority of patients were satisfied with their care but about a third felt that they had unmet needs most frequently relating to pain, fatigue and joint dysfunction. Interestingly those patients who reported unmet needs also reported significantly worse health status (Kjeken, Dagfinrud et al. 2006). It does suggest that more patient involvement during the consultation around making medical decisions could lead to improved outcomes. Patients need to be informed about medications and alternative options in order to feel competent to participate in such decisions (Cahill 2002). In 2010 EULAR convened a task force to develop a set of recommendations for the management of Rheumatoid Arthritis, aiming at a treatment target of remission or low disease activity. The objective of the task force was to formulate a consensus on a set of recommendations aimed at improving the management of Rheumatoid Arthritis in clinical practice. The consensus finding was based on evidence obtained from a systematic literature review that revealed improved outcomes with strategic therapeutic approaches (Smolen, Aletaha et al. 2010). Recommendations were then presented for discussion, amendment and voting to more than 60 experts from Europe, North and Latin America, Japan and Australia, including five patient representatives. Table 2.8 shows the final recommendations for treating to target and it is interesting to note that the first recommendation was unanimously voted and reflects the growing importance among Clinicians of the need to involve patients in the decision-making around their care.

TABLE 2.8 THE 2016 EULAR RECOMMENDATIONS FOR THE TREATMENT OF RHEUMATOID ARTHRITIS (SMOLEN, LANDEWÉ ET AL. 2017)

Over Arching Principles
Treatment of patients with Rheumatoid Arthritis should aim at the best care and must be based on a shared decision between the patient and the Rheumatologist
Treatment decisions are based on disease activity and factors such as progression of structural damage, comorbidities and patient safety
Costs of care should be considered
Recommendations
Treatment with DMARDS should start as soon as the diagnosis is made
Treatment targets should be sustained remission or low disease activity
Monitoring should be every one to three months during active disease, if no improvement after three months, or the target has not been achieved by 6 months, therapy should be adjusted
Methotrexate should be part of the first treatment strategy
If Methotrexate is contraindicated or the patient is intolerant, then Leflunomide or Sulphasalazine should be considered instead
Short term steroids should be considered
If the treatment target is not achieved with the first DMARD then other DMARDs should be considered
Biologics therapies should be considered if the treatment strategy with DMARDs has not achieved the target
If the patient is in persistent remission tapering treatment could be considered

The treatment target of remission or at least, low disease activity is measured by a Disease Activity Score (DAS). The score is a calculation based on an assessment of pain and swelling of the patient's joints, a patient rated score of their disease activity and a blood test to assess inflammation (Van Riel 2014). A score of greater than 5.1 implies that there is active disease, a score of less than 3.2 represents low disease activity and a score of less than 2.6 represents remission (Fransen and Van Riel 2009). Therefore, the aim of treat to target is a

DAS of less than 3.2. The 2016 EULAR recommendations (Smolen, Landewé et al. 2017) state that the treatment of patients with Rheumatoid Arthritis must be based on shared decision-making between the patient and the Rheumatologist.

2.4 The Evolution of the Rheumatology Specialist nurse

Over the last 30 years the care of Rheumatology patients has moved from a predominantly doctor-based outpatient service and rehabilitation in-patient service, to a multi-disciplinary outpatient-based service. For people with Rheumatoid Arthritis, the Specialist Nurse has become a key co-ordinating person within the team, as promoted by the British Society of Rheumatology (BSR) guidelines for the treatment of Rheumatoid Arthritis (Deighton et al 2008) where a "named" nurse to coordinate treatment was recommended. This has been accompanied by a substantial increase in the number of Specialist Rheumatology Specialist nurses in post in the NHS and the roles they undertake (Royal College of Nursing 2009). The following sections will review the development of the Rheumatology Specialist nurses' role and the increased responsibilities which were undertaken; shared decision-making and the impact of this on patient management; the current literature around patient knowledge of Methotrexate; nurses' knowledge of Methotrexate and a discussion of literature concerning consultation models and the relevance of those models to the nurses' and patients' interactions.

2.4.1 Development of the Role

The first Rheumatology Specialist nurse roles evolved within the National Health Service in the 1980s and they carried out functions such as assessing joint swelling, mobility and function (Bird 1981). As the development of the new drugs and their use increased, so the role of the Specialist Nurse evolved, with nurses gradually taking on the role of monitoring side effects of drugs and patient education (Hill, 1985, 1992). By 1997 duties that were once carried out by junior doctors were now provided by the Specialist Nurse (Flasher 1997).

More areas for service provision were identified and nurses' skills extended. Mullally (2001), Chief Nursing Officer for England in 2001, identified ten key roles for nurses (Table 2.9).

Table 2.9 The 10 Key Roles for Nurses (Mullally 2001)

1.	To order diagnostic investigations such as pathology tests and xrays.
2.	To make and receive referrals direct, say to a therapist or a pain consultant.
3.	To admit and discharge patients for specified conditions and with agreed protocols.
4.	To manage patients for specific conditions and within agreed protocols.
5.	To run clinics, say for ophthalmology or dermatology.
6.	To prescribe medicines and treatments.
7.	To carry out a wide range of resuscitation procedures and defibrillation.
8.	To perform minor surgery and outpatient procedures.
9.	To triage patients using the latest information technology to the most appropriate health professional.
10.	To take the lead in the way local health services are organised and in the way that they run.

Carr et al (2001) carried out a survey to explore the extended role of Allied Healthcare Professionals in Rheumatology and revealed that not only were Rheumatology Specialist nurses already fulfilling the 10 key roles outlined by Mullally (2001), but had incorporated other roles (Hill, Thorpe et al. 2003) such as joint examinations, assessing disease status, formulating and implementing disease management plans, referring to other healthcare professionals, recommending changes of drug therapy and addressing physical and psychological needs.

By 2006, nurses were also undertaking nurse prescribing and teaching medical students (Goh, Samanta et al. 2006). In 2009 the Royal College of Nursing (RCN) published the results of a survey in which they explored the performance and activity of Rheumatology Specialist nurses (2009). This report found that nurses had increased the number of clinics they were running per week, and they were now undertaking cognitive behavioural therapy and biomechanical assessments. In terms of the qualifications that the nurses had to undertake these tasks, the RCN 2009 survey found that a number of different courses had been undertaken. What it didn't highlight was the restriction that the limited geographical siting of the courses placed on nurse participation. At the time of writing there are nine postgraduate Rheumatology courses, six of these are aimed at doctors and the other three include Specialist nurses. These three courses are at Kings College London, Keele University, and the University of South Wales. Geographical access may limit most nurses and there are only a finite number of places on each course, which is open not just to nurses, but all healthcare professionals. There are therefore likely a large number of nurses in the UK with little opportunity to undertake any postgraduate training in Rheumatology. At the time of the Royal College of Nursing report (Royal College of Nursing 2009) it was narrated that the Rheumatology Nursing Forum had 1,216 members and that the British Society of Healthcare Professionals in Rheumatology had 554 members. These figures only represent a proportion of Rheumatology Specialist nurses in the UK as membership to these bodies is not compulsory. The Royal College of Nursing report (Royal College of Nursing 2009) also highlighted the wide range of tasks performed by these nurses and the wide range of pay bands of the nurses carrying out those tasks. This seems to suggest that the Rheumatology nurse role has evolved differently in various parts of the country. There appeared to be little uniformity in that role and little agreed education to meet the varying professional needs to carry out that role.

Shields et al (2012) commented on the standard of nurse training in England. The level of education for a nurse training then was Diploma standard, as opposed to the all-degree educated profession characteristic of Scotland and Wales at that time. They considered that this training lagged behind most of the world, commenting that opportunities to progress the training to degree level in England were abandoned in order to maintain a high supply of poorly paid nurses to work on the wards of the NHS. However, a white paper published

2010, ”Front Line Care: A Report by the Prime Ministers Commission on the Future of Nursing and Midwifery in England” which predicted that all new nurses in England would hold a degree level qualification by 2013 (Department of Health 2010). The Nursing and Midwifery Council (NMC) developed the content and standards of proficiency for the degree course, which are regularly reviewed to ensure they remain fit for purpose. These standards specify the skills and knowledge that registered nurses must have in order to deliver safe, compassionate and effective nursing care. There is no national curriculum for the training of new nurses, however, educational institutions running the training courses must ensure that the curriculum they provide complies with all of the standards. The standards are grouped into seven platforms (Table 2.10) followed by two annexes with communication only appearing in Annex A (Nursing and Midwifery Council 2018) (Appendix 2).

TABLE 2. 9 THE NMC STANDARDS (NURSING AND MIDWIFERY COUNCIL 2018)

1.	Being an accountable professional
2.	Promoting health and preventing ill health
3.	Assessing needs and planning care
4.	Providing and evaluating care
5.	Leading and managing nursing care and working in teams
6.	Improving safety and quality of care
7.	Co-ordinating care
Annexe A	Communication and relationship management skills
Annexe B	Nursing Procedures

This appears to suggest that communication skills are less important in some fields of nursing than others and the standards described in Annexe A whilst having all of the

elements of communication required to conduct a consultation, there is no onus on developing consultation skills as part of nurse training. The NMC clearly recognises the importance of communication as they comment:

> *"Effective communication is central to the provision of safe and compassionate person-centred care. Registered nurses in all fields of nursing practice must be able to demonstrate the ability to communicate and manage relationships with people of all ages with a range of mental, physical, cognitive and behavioural health challenges"* (NMC, 2018).

The NMC further highlights the importance of expertise and knowledge recognising that there may be varying levels required depending on the field of practice that the nurse is working in:

> *"…the level of expertise and knowledge required will vary depending on the chosen field of practice".*

It is also clear that the NMC Approved Educational Authority (AEI) are responsible for ensuring that nurse education programmes meet their standards (Leigh and Roberts 2018). The AEI is also responsible for ensuring that the practice experience received by student nurses is of the highest quality; which will be assessed by the practice supervisor assessor. The NMC intend that the qualified nurses in each learning area will carry out the practice supervisor and assessor roles. The AEIs are responsible for ensuring that these nurses are equipped to carry out these functions. However, in this age of overburdened, overworked and understaffed nursing personnel (Massey, Esain et al. 2009) the added responsibility of supporting the learning experience of the student nurse could be very challenging. Also, it could be said that the learning experience will only be as good as the person providing it and the environment in which they are. The NMC does not categorically state that student nurses need to understand good consultation techniques; therefore, it will not be a priority in the learning environment, which could have an impact post qualification when that nurse is faced with carrying out consultations.

2.5 Shared Decision-Making

The integration of patient education into the communication between healthcare professional and patient has evolved over the last 60 years (Hoving, Visser et al. 2010). Hoving et al describe the physician as the ultimate authority who was responsible for the diagnosis, treatment and healing of patients in the 1960s and 70s. The patient had a passive role and even decisions to tell patients who were terminally ill about their prognosis was left up to the physician. This paternalistic approach to patient care continued throughout the 1960s and 1970s but began to change in the 1980s, which saw a growth of patient advocacy and legal rights to be informed about health condition and treatments (Deccache and Aujoulat 2001). Patients were now becoming more actively involved in improving their own health by making lifestyle changes which resulted from patient education by healthcare professionals (Hoving, Visser et al. 2010). The 1990s saw further development of the role of patients in their own disease management (Hoving, Visser et al. 2010); patients were now being taught skills on how to self-manage their diseases, and the physician was no longer always being seen as the ultimate authority, the relationship between physician and patient was becoming more equal. Families and the broader social network of patients were now being recognised as having a contribution to disease management and behaviour change interventions (Cohen, Hyland et al. 1999). The development of the internet also resulted in patients being able to look up information for themselves and became more informed (Ullrich Jr and Vaccaro 2002, McMullan 2006).

Sassen (2018) describes three steps which lead to optimal health management for patients; disease prevention, the aim of which is to prevent health problems but if they are already present, then to manage those health issues in order to prevent further deterioration. Patient education, the aim of which is to optimise behaviour in order to deal with health issues, and self-management which focusses on how patients manage their own health. Rheumatoid Arthritis is not necessarily a preventable disease, and the possible contributory factors leading to the onset of Rheumatoid Arthritis have already been discussed in this Chapter, and it has already been shown that smoking and overweight can contribute to the onset of Rheumatoid Arthritis (de Hair, Landewé et al. 2013). Thus, patient education around smoking and obesity could prevent or delay the onset of this disease.

Patient education is a complex process which is intended to facilitate learning and improve health outcomes (Flanders 2018) and it is based on several foundations; professional, social and economic and political and legislative (Deccache and van Ballekom 2010). It is closely related to disease prevention and is aimed at optimising behaviour to improve health status and deal with health problems (Sassen 2018). Sassen believes that patient education should be about the interaction between the health problem that patient has and their behaviour towards it. It should fit the patient's lifestyle because dealing with health problems is often associated with lifestyle changes. Sassen also believes that it is important for patients to be able to think medically about their own health, which she terms as "proto-professionalizing". She believes that if patients are better informed about medical issues and health and have a better knowledge of the healthcare system, then this could empower them to communicate with healthcare professionals more effectively resulting in stronger, healthier behaviour.

The concept of patient self-management has been around for a while (Hanson and Gerber 1990), including self-management in Rheumatoid Arthritis. Hammond (1998) investigated common self-management techniques used by a cohort of 41 patients with Rheumatoid Arthritis, with only half of them recalling being given any self-management advice by their Rheumatology team, despite most having been given books and leaflets. She found that two thirds of the cohort used aids such as hot packs and rest on a daily basis, but exercise and joint protection was less used, even though the patients recognised the benefits. She reported that an increase in the amount of education people with Rheumatoid Arthritis received would increase the use of these self-management strategies.

A study by Chaleshgar-Kordasiabi et al (2018) conducted semi-structured interviews with 30 patients with Rheumatoid Arthritis, and revealed three main themes relating to barriers. The first theme was behavioural barriers, which included lack of awareness of self-management, lack of motivation and lack of belief in the process of self-management. The patients also reported that they felt the lack of a good physician-patient relationship and unavailability of good educational materials contributed to the barriers they faced. The second theme was described as environmental barriers, which included expenses, in-home equipment, their social situation and the educational status of the individual. The third theme identified was described as reinforcing factors, such as social and emotional support.

Some patients lost motivation to apply self-management techniques because they did not have family support.

Whilst these studies were conducted in the United States and Iran respectively they are still very much in line with a literature review of 26 studies which was conducted by Van Zanten et al (2015). They revealed that the most common barriers to self-management exercise was lack of time and cost, but arthritis specific barriers were fatigue and pain. Further barriers identified were the patient's lack of knowledge of the exercise regimes and lack of support from the healthcare provider. It appears that there are a number of barriers which some patients perceive as inhibitory to the application of self-management. But self-management is about identifying problems and looking at ways of solving those problems, by making shared decisions around options available to the patient and also fitting it into the patient's lifestyle. This shared decision-making involves both the patient and the healthcare professional equally considering the patient and their families and arriving at decisions for treatment where barriers can be overcome.

Shared decision-making is a process where patients and healthcare providers consider the various treatment options and patient preferences to reach a health management decision which is based on mutual agreement (Frosch and Kaplan 1999). The key principles of shared decision-making involve a process that includes at least two participants, the patient and the doctor. Additionally, this process could incorporate the patient's family and other healthcare professionals. Elwyn et al (2000) developed a series of steps for the development of shared decision-making (Table 2.11). They then developed a model of how to implement shared decision-making as they felt that there was a lack of guidance around how to apply the principles in practice (Elwyn, Frosch et al. 2012). Their model has three steps: Introducing choice; describing options and helping patients explore their own preferences and make decisions. This model is dependent on a process of negotiation with the patient, understanding what is important to them and developing options and preferences.

TABLE 2.10 STEPS FOR SHARED DECISION-MAKING (ELWYN ET AL 2000)

·	Develop a partnership with the patient · Establish or review the patient's preference for information, e.g. amount and format
·	Establish or review the patient's preferences for role in decision-making
·	Ascertain and respond to patients' ideas, concerns, and expectations
·	Identify choices and evaluate the research evidence in relation to the individual patient
·	Present (or direct to) evidence, considering the above steps, and help the patient reflect upon and assess the impact of alternative decisions with regard to their values and lifestyles
·	Make or negotiate a decision in partnership, manage conflict
·	Agree upon an action plan and complete arrangements for follow-up

Patients do not expect shared decision-making and generally they do not object if it does not take place, at least not to the physician (Godolphin 2009). Patients are generally disempowered in their encounters with physicians; they feel intimidated and unable to make a difference in the relationship, are reluctant to bother the doctor, especially in the current climate of belief that the healthcare system is "a wreck" (Godolphin 2009). Patients want to have a good rapport with health professionals, and they generally feel that this will contribute to their likelihood of getting good care. Patients tend to avoid assertiveness, which may jeopardize the rapport (Towle, Godolphin et al. 2003). This disempowerment of patients, when they confront the healthcare system, leads to misunderstandings and "wimpish" behaviours that can have important adverse outcomes (Britten, Stevenson et al. 2000, Berland 2007). But the doctor/nurse-patient relationship is changing. Society is changing into a more consumerist model, with better-informed patients (e.g., from their use of the Internet), a greater public involvement in healthcare institutions and a gradual movement away from paternalism and closer to the ethical imperative of autonomy (Coulter 2002). This shift towards the redistribution of power away from the physician and to the patient focussed on patient centred care (Castro, Van Regenmortel et al. 2016) in which the patient was considered empowered once they had the knowledge, skills and attitudes which

would influence their own health behaviour and therefore have a positive impact on their lives (Garattini and Padula 2018). The UK Government (Donaldson 2003) was the first in Europe to introduce the concept of the expert patient who should have full access to information which was critical to their healthcare. In 2015 a landmark court ruling made it clear that any intervention must be based on a shared-decision-making process and that the patient is aware of all options for treatment and is supported by the healthcare professional to make that choice (Ward, Kalsi et al. 2020) . This ruling was based on a case where a baby was born to a diabetic mother who had not been informed of the risks of a normal delivery despite raising concerns that her baby was large and she was small and she was not informed of other potential options, the baby suffered severe disabilities as a result and lead to the Montgomery Judgement (Montgomery and Montgomery 2016). However, whilst it is clear that shared-decision-making can have a positive impact on the lives of patients, adoption of this process has been slow because of perceived challenges to its implementation (Kalsi, Ward et al. 2019). Kalsi et al reviewed literature from different specialities which recognised the positive impact of shared-decision-making within those specialities, but highlighted challenges such as perceived lack of time, lack of quality support tools, lack of decision aid tools and cultural issues. Kalsi et al consider that support tools and training are needed to support clinicians in the shared-decision-making process. Garattini and Padula (2018) conducted a literature review of the expanding publications around patient empowerment, which is described by the World Health Organisation as (Garcimartin, Comin-Colet et al. 2017):

> *"a process through which people gain greater control over decisions and actions affecting their health".*

Garattini and Padula reviewed 129 articles published between 2000 and 2017 on patient empowerment and revealed that whilst patient empowerment is linked to higher literacy levels, it also required behavioural change and without this, it can lead to an over-dependent on physicians, regardless of the level of literacy. They also indicated that data from two surveys in coronary care units and palliative care, showed that most patients were content to leave the decision-making to their healthcare professionals and had no desire to take part in this process. It is therefore an important consideration to ensure that the

patient actually wants to take part in decision-making and may actually prefer a paternalistic model of care.

2.5.1 Shared Decision-Making in Patients with Rheumatoid Arthritis

In order for patients to develop more collaborative relationships with their physicians and nurses to empower them to negotiate targets for treatment they need to be more informed about their own disease. Helliwell et al (1999) carried out a 12 month study on a group of patients diagnosed with early Rheumatoid Arthritis. The objective was to determine whether educational programmes not only imparted knowledge, which empowered the patient, but also to establish whether that knowledge changed behaviour. The outcome measures were radiological examination and quality of life assessments using questionnaires. There was a cohort of 34 patients for the control group and 43 patients for the education group who were to receive a four-week education programme; all patients had Rheumatoid Arthritis for less than five years. The education group showed a significant improvement in general health perception and social functioning. There was no significant difference in outpatient visits and in-hospital admissions between the control group and the education group but the education group showed a slight increase in changes of second line drug therapy for their disease. The education group also showed a slightly better radiological progression than the control group which may relate to improved self-care, better strategies for joint protection and possibly better drug compliance. Although this was a small study, it does illustrate a trend that better education could lead to improved disease outcome for the patient. However, most patients do not receive a four-week education course when they have been diagnosed with Rheumatoid Arthritis, they usually receive a booklet describing Rheumatoid Arthritis produced by Arthritis Research UK (formerly Arthritis Research Campaign ARC) which is widely used throughout the country by Rheumatology services. Walker et al (2007) carried out an interesting study comparing the use of the booklet (see Appendix 3) with a mind map describing Rheumatoid Arthritis (see Appendix 4) and further work was carried out by Robinson et al (2007). Walker et al consider that patient education has become an integral part of the therapeutic approach to helping patients with Rheumatoid Arthritis to self-manage their arthritis. They believe it is integral to

the promotion of both adherence and safety in relation to what are now complex treatment regimes. They feel that accessibility of educational material is key to successful knowledge transfer and low levels of literacy may limit understanding of traditional forms of patient information.

A further aspect of the interface between patient and healthcare professional is the written information which is given. This information forms an essential part of the communication with patients about their drug treatment. The information in the form of booklets, are produced by Versus Arthritis and are written for patients. They contain information on rheumatological diseases, treatments, coping strategies and provide answers to common questions. It is important to consider these sources of patient information as they are integral to the management of patients with Rheumatoid Arthritis (Walker, Adebajo et al. 2007). Walker et al consider that not only are the booklets an important source of information for patients, but that it is also essential to consider their literacy status. A study in Glasgow (Gordon, Hampson et al. 2002) showed that one in six of their RA patients were functionally illiterate. This could indicate that around 16% of patients with Rheumatoid Arthritis may be functionally illiterate, suggesting that a booklet format may not be the most appropriate education tool. Arthritis Research UK (now Versus Arthritis) produced pictorial mind maps based on some of the booklets. The concept of mind mapping was developed by Buzan and Buzan (2006). Information is presented in diagram form and it uses key words and images, which explode from a central theme in a format that aids cognitive processing. In this way the mind map can focus on meaning and therefore grammar becomes less important which could indicate that this technique may be more appropriate for less able readers. Mind maps have generally been used as a study technique in educational settings to aid revision. They have been shown to improve the recall of factual knowledge by 10–15% in a randomized study of medical students with follow-up at one week (Farrand, Hussain et al. 2002). However, in a study of the effect of three different patient education methods on recall in orthodontic patients, small but significant advantages in recall gained through the use of mind maps were not maintained at six weeks (Thickett and Newton 2006).

Walker et al (2007) recruited a cohort of 363 patients with Rheumatoid Arthritis. Their reading ability was assessed using the REALM score (see Appendix 5) and they also completed knowledge scale questionnaire for Rheumatoid Arthritis. Patients were

randomized into two groups; one group received the booklet alone and the other group received the booklet and the mind map. They were given a week to read the material and then knowledge scale questionnaire was repeated over the telephone. The outcome of the study was that Walker et al were unable to show any significant increase of knowledge of poor readers using the mind map. The effect of the mind map appeared to increase the knowledge of the better readers. Walker et al reasoned that the poor readers, who also had poor educational attainment, were unable to improve their knowledge with either format of information that could relate more to understanding than simply literacy.

The work by Walker et al (2007) and others have highlighted how complex it is to impart knowledge and achieve understanding for some patients. They revealed that around 16% of the Rheumatoid Arthritis population have poor reading ability, which is a significant number, similar to that in Glasgow (Gordon et al 2002), and this must be recognized by healthcare professionals when they are negotiating treatment targets. This figure reflects the national statistics on adult literacy in the UK; The National Literacy Trust (2021) have published literacy statistics for the four nations in the UK. In England 16.4% of adults are considered to have very poor literacy skills, in Wales 12% lack basic literacy skills, in Scotland 26.7% of adults experience challenges due to their lack of literacy skills and in Northern Ireland 17.9% of adults have very poor literacy skills. Everyone has their own framework of perception and ability to retain and understand knowledge and healthcare professionals need to adopt negotiation techniques, which are appropriate to that person in order to achieve a shared goal for treatment. More recently, Barton et al (2014) designed a cross sectional study to explore whether English language proficiency, health literacy and trust in the physician impacted on shared decision-making in patients with Rheumatoid Arthritis. They conducted telephone interviews with two cohorts of patients from two different areas of America, the RA Panel (n= 275) based in Northern California and the UCSF RA Cohort (n= 234) which was based in San Francisco. The characteristics of each cohort were very different; the RA Panel were predominantly white and all spoke English as their first language whereas the UCSF RA Cohort spoke English (64%) Spanish (22%) Chinese (14%) as their first languages and 39% had limited English language proficiency. Further only 5% of the RA Panel had less than high school education, whilst it was 28% for the UCSF RA Cohort. Also, the RA Panel appear to have had a higher disease duration with an average of 26 years compared to twelve years in

the UCSF RA Cohort. Interestingly, whilst both cohorts reported a high degree of trust in their physicians, low trust in the physician was associated with suboptimal shared decision-making in both cohorts but lower education attainment was associated with suboptimal shared decision-making in the UCSF RA cohort. However, worse global ratings of disease were associated with the RA Panel. Whilst the study reported that about one third of all patients reported suboptimal shared decision-making, it is unclear how much the patients themselves understood the processes of shared decision-making and their expectations of their consultation with their clinician. Further, this study reviewed physicians only, therefore whilst it is useful to identify groups which may require more understanding and support in the shared-decision-making process, it is unclear what the impact of a nursing intervention may have had on this population.

Rowlands et al (2015) conducted an observational study to assess the literacy and numeracy skills which are required in order to understand commonly used health information materials in England. 64 examples of health information were used in the study, all contained text and 50 contained numeracy. They found that 43% of the population who completed the study fell below the competency threshold expected to be achieved by the age of 16 for literacy and 61% were below the literacy and numeracy threshold. They concluded that health educational materials were too complex to be understood by a significant proportion of the population and rigour should be applied when developing these materials in order to ensure they meet the needs of all groups. This further reinforces the importance of ensuring that information given to patients should be tailored to suit each individual patient's needs.

A European League Against Rheumatism (EULAR) task force was convened (Zangi, Ndosi et al. 2015) to develop a set of recommendations to inform patient education for people with inflammatory arthritis, to identify the need for further research and to define the educational needs of healthcare professionals to provide evidence based patient education, thus ensuring that shared decision-making practice was at the core of all patient education. The overarching principles of the recommendations are:

1. Patient education is a planned interactive learning process designed to support and enable people to manage their life with inflammatory arthritis and optimise their health and well-being.

2. Communication and shared-decision-making between people with inflammatory arthritis and their healthcare professionals are essential for effective patient education.

Following a systematic literature review, the EULAR task force developed 8 recommendations (Table 2.12).

TABLE 2. 11 EULAR RECOMMENDATIONS FOR PATIENT EDUCATION FOR PEOPLE WITH INFLAMMATORY ARTHRITIS (ZANGI, NDOSI ET AL. 2015)

	Recommendation
1	Patient education should be provided for people with inflammatory arthritis as an integral part of standard care in order to increase patient involvement in disease management and health promotion
2	All people with inflammatory arthritis should have access to and be offered education throughout the course of their disease
3	The content and delivery of education should be individually tailored and needs-based
4	Education should include individual and/or group sessions through face-to-face, online, phone calls, written and multimedia resources
5	Education programmes should have a theoretical framework and be evidence based
6	The effectiveness of this education should be evaluated and outcomes used must reflect the objectives of the patient education outcome
7	Education should be delivered by competent healthcare professionals and/or trained patients, if appropriate, in a multidisciplinary team
8	Providers of education should have access to and undertake specific training in order to obtain and maintain knowledge and skills

However, the EULAR task force recognised that the effective implementation and evaluation of these eight recommendations will require a clear implementation strategy and appropriate training and support must be provided. But they do conclude that the dissemination and application of these recommendations could lead to the establishment of core standards for patient education across Europe.

Miedany et al (2016) recognised that several shared decision-making tools had been developed in other disease areas, but there was a lack of focus in the area of chronic arthritic disease management. They developed a study to develop a shared decision-making tool which would inform patients about their ongoing disease activities and the risks and benefits associated with their drug therapies. They hypothesized that this decision aid would result in more effective treatment decisions enhancing patient care. They further assessed an online version of the shared decision-making tool and postulated that it could improve patients' compliance and adherence to their treatment therapies. The shared decision-making tool was piloted twice, firstly to test language and formatting to ensure it would be acceptable to the target population and easy to complete, and secondly to test the tool in a clinical setting which would allow the researchers to calculate the sample size for the study. The target population were patients with inflammatory arthritic conditions such as Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis, who were to start a new treatment, either a disease modifying drug or biologic therapy. 174 patients comprised the study group and 172 patients were involved in the control group who received standard care. Patients were randomised into each group and all patients had access to a telephone line. Half of the patients in the study group received the paper version of the tool and half used the on-line version. It was unclear how the tool was presented to the patients and when it was given. All patients undertook the standard care model of three-monthly reviews for twelve months, but they were instructed not to reveal which group they had been randomised into; therefore, the shared decision-making tool appears not to have been discussed with the clinician. Whilst the researchers reported that every participant in the study completed a five-item questionnaire at the end of 12 months, two these five items were based on their experiences using the shared decision-making tool. Further, the questionnaire appears to have consisted of five questions; did the shared decision-making tool help you understand effect of the treatment on disease activity; did the shared

decision-making aid motivate you to take medication; trust in the treating doctor; concerns about the future; coping with daily life. Responses were made using a visual analogue scale. The researchers concluded that the tool helped the healthcare professional to share information with the patient in an evidence based, standardized format, and they showed that patients who had gained more knowledge were more confident and more involved. The weakness of this study was their outcome measure. The design of the five-item questionnaire was brief and yielded little to discuss, in fact there was little discussion of their results in the text. Further, it was unclear how the shared decision-making tool was administered and who was involved. Moreover, whilst the researchers described this as a shared decision-making tool, there was no description of that shared decision-making process between the patient and the healthcare professional. This could be a useful tool to prepare the patient for the consultation and give them information, but it was not used with the healthcare professional and patient to enhance the shared decision-making process.

Robinson et al (2010) completed a survey of 100 patients. A number of questions were put to them around expectations of treatment and their understanding a Disease Activity Score (DAS 28) [which is a calculation based on the number of tender and swollen joints the patient has, an assessment of how the patient regards their disease activity on a one to ten visual analogue scale and a blood test measuring amount of inflammation the patient has]. Some of the patients surveyed were taking part in a study where monthly DAS 28 scores were carried out and therefore may have been familiar with their DAS score. However, out of all of the patients surveyed only one person reported that they had heard of the DAS score but they were unsure what it actually meant. A series of questions were asked on how the patients would define the best outcome of treatment for them. All patients eventually negotiated a treatment target of an activity that they could currently carry out and would like to continue with. Or an activity that they could once perform, but could no longer partake in because of the restrictions of their Rheumatoid Arthritis. Once the target for treatment was agreed between the patient and the healthcare professional, it was recorded in the patient notes and treatment was tailored in order to reach that target. When the patient returned for review, the target for treatment was discussed with the patient to ensure that it had been met and treatment could be altered if necessary. Whilst this

method was easy to apply during the consultation, the survey did not provide longer term data to evaluate the impact of negotiating a treatment target with the patient in this way.

A systematic review of randomised and non-randomised trials was conducted by Legare et al (2018) aimed to determine whether healthcare professionals involved patients in decisions about their care, and whether it was effective, They analysed 87 identifying which activities were most successful in helping healthcare professionals involve patients in their care. They concluded that the studies revealed that many different activities to increase shared decision-making by healthcare professionals were adopted, but they could not conclusively say that these activities made an impact in shared decision-making. However, they did comment that the quality of the evidence was inadequate, often poorly reported and that there were many potential sources of error in the results of the studies. A study carried out in Holland by Mathijssen et al (2020) audio recorded routine consultations with 168 different patients with Rheumatoid Arthritis. The level of shared decision-making was scored using the OPTION scale which is based on five items; the justification of the decision-making, ie that alternative treatments or management exists; justification of working as a team, ie that the clinician will support the patient to become informed; describes options and checks understanding; the clinician makes an effort to determine patient preferences in response to the provided options; the clinician works with the patient in order to integrate the patient;' preferences as decisions are made. Each of these items were scored on a five-point scale from zero to four. The researchers found that only a low to moderate level of shared decision-making was implemented in the care of patients with Rheumatoid Arthritis. The level of shared decision-making varied with the type of treatment or management being discussed and the length of the consultation, longer consultations, tended to score higher. They concluded that there is room for improvement in the use of shared decision-making. It was not clear whether any Specialist nurses had carried out any of the consultations, as throughout the paper the word "clinician" was used. However Mathijssen et al (2020) did conduct an online survey of 77 Rheumatologists and 70 nurses to explore knowledge and attitudes to shared decision-making. They concluded that whilst most of the healthcare professionals lacked a full understanding of the concept of shared decision-making, 92% of Rheumatologists and 100% of nurses were very positive about the notion of shared decision-making and believed it would lead to improved treatment adherence by patients. It does

appear that whilst there is general agreement amongst healthcare professionals that shared decision-making could make an impact on the management of patients with Rheumatoid Arthritis, more training and education is required in order for this to be applied during the consultation process.

The literature has revealed that through patient education, individuals can become more empowered leading to a greater understanding of their disease which could necessitate lifestyle changes. It also reveals the impact that shared decision-making can make on these processes of understanding and change. However, it seems clear that not all healthcare professionals apply these practices in their management of patients with Rheumatoid Arthritis and other diseases (Légaré, Adekpedjou et al. 2018, Mathijssen, Vriezekolk et al. 2020). Further, the significance of considering the written information given to patients is an important part of this thesis. There is a sustained lack of literature around how nurses impart information to patients, and whether a shared decision-making process is applied. This thesis therefore, aims to explore the process nurses employ in that information exchange about Methotrexate with patients, starting this therapy. Written information in the form of a booklet may be a fundamental part of that process and an understanding how nurses use these booklets and how effective that process is, is a principal consideration and therefore warrants further exploration.

2.6 Knowledge

The subject of knowledge and how it is acquired is a wide-ranging topic and outside the scope of this thesis. Therefore, this section will briefly define knowledge in the context of how nurses acquire knowledge and skills in order to carry out their roles. Further discussion will examine how they assess their own clinical competency to ensure that they have the knowledge to deliver to the patients thus empowering them to make informed decisions and choices.

2.6.1 Definition of Knowledge

The term “knowledge” is an abstract yet powerful concept but so far is without a well-defined definition (Bolisani and Bratianu 2018). Dombrowski et al (2013) provide three definitions of knowledge which are applicable within the context of this thesis and will be further investigated; experiential knowledge – that knowledge which is gained from our environments and sensory experiences: skills – hands on knowledge, those physical tasks that we have learned to do: knowledge claims – this is knowledge that we know, or think we know, which is learned from books or at school.

The Dreyfus model of skills acquisition is a model of how experiential skills are acquired through formal instruction and practice and was developed by Dreyfus and Dreyfus (1980). Dreyfus and Dreyfus consider that the novice strictly adheres to taught rules and does not exercise discretionary judgement. They described the advanced beginner has having limited perception around circumstances and treats all aspects of work with equal importance, but the competent learner can cope with multiple activities, and has developed perceptions in relations to goals. They also consider that the learner can also plan and formulate routines. And that the proficient learner can view a situation holistically and prioritise what is important. The proficient learner can also think outside the box and adapt to a situation if it is required. Dreyfus and Dreyfus describe the expert as not needing to rely on rules and guidelines; that they have a deep and intuitive understanding of situations, visualising possibilities and uses an analytical approach when confronted with new situations or problems.

Benner (1984) is one of the main proponents of this model for the development of skills acquisition in nursing practice. She describes knowledge as either being formal and explicit as opposed to involving practical reasoning and intuition; which is embedded in practice. Benner describes three studies conducted between 1982 and 1997 in which nurses of varying experience and skills in adult intensive care units (Benner 2004) were interviewed. These were US based studies, the first involving 83 nurses and six preceptors from six different hospitals; the second 130 nurses and the third a further 75 nurses extending study two. The participants were selected based on the number of years they had been qualified and for those who had been qualified over five years, their supervisors were asked to

consider the quality of the nurses' practice. The nurses were interviewed about situations they had been in and their responses to those situations. Benner applied these responses to the Dreyfus model, which were largely in concordance with the developing processes from novice to expert. However, it was not clear how long each nurse took to reach the expert level of competence. Dreyfus and Dreyfus (1980) do not describe or apply a timeframe to the model, but there appears to be an assumption by Benner that it takes time to gain the experience needed to develop insights and intuition which will result in expert competency. It was also unclear how many of those nurses had indeed gone on to do further training post qualification which may have resulted in requiring less time to gain the confidence and experience required to achieving expert knowledge. Indeed, Cash's interpretation of Benner's earlier work, expresses that it fossilises nursing practice and minimises nursing knowledge (Cash 1995).

Richards and Hubbert (2007) conducted a study of the experiences of expert nurses in caring for patients with postoperative pain, and based on Benner's study (Benner 2004) they interpreted an expert nurse as being qualified for over five years working in the same area. This perspective appears to negate the need for nurses to undergo any postgraduate training, it seems to describe that after five years working in one place a nurse will then become an expert. Later studies, for example Bringsvor et al (2014) undertook an interview survey of intensive care nurses in Norway exploring their sources of knowledge focussing on evidence-based practice. All of the participants had undertaken 18 months of postgraduate education to specialise as ITU nurses and there was a wide variation in experience from three months to more than thirty years. There was no indication of what that postgraduate training had consisted of and when the individuals had carried out that training. Because the breadth of experience from three months to over 30 years was so wide it does raise a possible variance of training which could impact on their results. It is also not clear whether the length of time the participants had worked on ITU or the length of time they had been qualified influenced their responses in terms of evidence-based knowledge and experiential learning. However, the study did attempt to balance the importance of having a scientific evidence-based approach to practice as well as an intuitive, experiential perspective. It has been suggested that experience alone is not enough. Postgraduate training for nurses and specialisation results in increased confidence, critical thinking and a sense of having a more

equal weighting amongst their professional colleagues (Graue, Rasmussen et al. 2015). In a recent large scale European study, Wangensteen et al (2018) carried out a survey of nurses undertaking postgraduate programmes in different treatment areas across Europe. The aim of the study was to describe nurses' self-assessment of their clinical competency and they rated themselves most highly when taking full responsibility for their own actions. They rated themselves less in areas such as medication interactions, identification of differential diagnoses and giving health promotion advice. This suggests that nurses are less confident in areas, which require more scientific knowledge. The implication of this does advocate the importance of having sound knowledge foundations in areas such as giving patients information about toxic drugs such as Methotrexate in order for nurses to competently give information to patients.

2.6.2 What do patients need to know about Methotrexate?

Formal studies of what information patients need to take drugs safely and effectively are difficult to perform and therefore rare. There is evidence that understanding why a drug is prescribed and the importance of taking it per the prescription improves adherence to that drug (Hill, Bird et al. 2001). Education, both verbal and written, can reinforce beliefs about the necessity of the drug, but may increase fear of side effects and a dissonance may arise between beliefs and experience (Hayden, Tarrant et al. 2014). Decision aids to help patients decide whether to take Methotrexate are popular in the USA and also provide education, but mainly on the theoretical benefits and toxicities (Li, Adam et al. 2013). A study conducted by Sowden et al (2012) involved 51 patients taking Methotrexate and 94% had documented evidence of being given Methotrexate education. A combination of interviews, patient notes reviews and patient administered questionnaires revealed that only 11.8% of the patients recognised potentially dangerous drug interactions and less than 60% recognised possible major adverse events associated with Methotrexate. Therefore, despite consistent baseline education, end-user knowledge appears to be limited.

Patients need knowledge in order to make informed decisions and choices. They require information around how to take drugs, how often they should take the medicine and the

number of tablets they need to take. They require information around the importance blood monitoring for safety and how to access this service. It is important that patients have information around what to expect in terms of drug efficacy and how to recognise indications of side effects and how to deal with these and how to report them. It is vital that patients understand the impact of taking Methotrexate on their health as it could, for example, render them more susceptible to infections and possible drug interactions (Boerbooms, Kerstens et al. 1995, Gaies, Jebabli et al. 2012). Therefore, they need to know how to minimise those risks by consuming less alcohol, receiving recommended immunisations and thinking carefully about planning pregnancies, which could mean stopping the drug for a period of time. Some patients want more information about how the drug works, others are not interested. A cross-sectional study of 600 patient or carer interviews carried out by Krueger et al (2011) showed that only 58% of patients wanted information about adverse reactions, 32% wanted information around basic instructions and 31% wanted information on drug interactions. The study also revealed that a review of information at a later opportunity was more likely to be requested by those patients who had higher educational achievements. It does indicate that the information given should be tailored to the individual needs of the patient. The Versus Arthritis booklet on Methotrexate (Versus Arthritis 2019) was designed as an information booklet for patients. The booklet is divided into sections:

- What is Methotrexate and how is it used?
- Is Methotrexate suitable for me?
- When and how do I take Methotrexate?
- Possible risks and side effects
- Taking other medicines
- Vaccinations
- Having an operation
- Alcohol
- Fertility, pregnancy and breastfeeding.

As discussed previously in this chapter, the main issues a patient could be challenged with are covered in this booklet, but it needs to be supplemented by information about the local

service, such as help-line telephone numbers and how the monitoring system works. It is clear that a substantial amount of information is required for the patient to make informed decisions and choices and remain safe on the drug. Therefore, patients need to fully understand the information given to them and the nurses' role is to facilitate this understanding which is the focus of this thesis.

2.6.3 Nurses' Knowledge of Methotrexate

EULAR make clear recommendations around the education of patients with Inflammatory Arthritis (Zangi, Ndosi et al. 2015), but they also highlight that applying these recommendations effectively will require appropriate training and support. They conclude that the dissemination and application of these recommendations could lead to the establishment of core training standards for giving patient education across Europe, which implies that there are no current core standards for Rheumatology Specialist nurses. Therefore, this section will review the literature to discuss the current position regarding the training and knowledge Rheumatology Specialist nurses have in order to give information about Methotrexate to patients.

It has been recognised that patients require a certain depth of knowledge in order to take Methotrexate safely and as prescribed (Al-Awadhi, Dale et al. 1993, Burma, Rachow et al. 1996). More recently Sowden et al (2012) undertook an audit of patients who were prescribed Methotrexate, 94.1% of whom had been given their education by a nurse. Only 11.8% recognised major side effects, which could be related to Methotrexate, concluding that patients require regular knowledge testing in order to address the lack of core knowledge. However, what was not clear was how the information had been given to the patients and how those nurses had been trained and assessed for competency. Fayet et al (2016) conducted a survey of patient knowledge in 183 patients who were taking Methotrexate, and concluded that patients have poor knowledge of the serious side effects such as pneumonitis (36%) and Trimethoprim interaction (21%), of Methotrexate and they also recognised that few studies have been published in this area. Most of the patients in their survey had been given the information by their Rheumatologists only, and had not had

a dedicated session for this process. Additionally, Fayet et al did not describe the process of information giving or whether the patient had received any written information. Fayet et al concluded that using different therapeutic educational tools was indicated to improve the knowledge base of patients taking Methotrexate. However, they fail to identify what those tools should be and any justification for their statement. They did observe that the group with the poorest knowledge base were older less educated people. Perhaps this highlights that education should be tailored around the individual rather than "one size fits all". It could therefore be argued that these types of sessions around information giving should be delivered by a health care professional, with the appropriate educational underpinnings of Methotrexate and the ability to tailor that session around the individual person. As previously discussed in this chapter, education should be tailored to fit the individual (Sassen 2018), one size does not fit all and it is therefore not surprising that studies such as that undertaken by Fayet et al (2016) revealed differences in the amount of knowledge individuals retain from different age groups and educational status. This literature review has revealed little documented evidence of the processes undertaken when the Rheumatology Specialist nurses deliver information to patients about Methotrexate and whether the patients have actually understood that information. Therefore, due to the limitations highlighted in this chapter, the current study will explore the process by which nurses transfer knowledge and understanding to the patients. This will include exploring consultation skills within the nurse-patient encounter.

2.7 Consultations

2.7.1 Definition of a Consultation

The word "consultation" can have several meanings; "a discussion between people or groups before they make a decision"; "in consultation with someone"; "a meeting in which people or groups have a discussion before decisions are made"; "a meeting with an expert or a professional person to get advice or discuss a problem, especially a meeting with a doctor"; "the process of getting advice from an expert or a professional person"' "the process of looking in a book or at a map or list in order to find information" (Cambridge 2020). The

traditional understanding of a medical consultation in the NHS was that of a paternalistic interaction between a doctor and a patient (Hoving, Visser et al. 2010), as previously discussed in this chapter. But as the roles of Nurses and AHPs expanded there was a growing recognition that nurses and AHPs should be developing consultation skills; which would lead to more meaningful interventions benefiting patient care (Termini and Ciechoski 1981). However, Termini and Ciechoski describe the context of the consultation as leaning towards emotional/psychological support for patients and their families. In 1983 Bird (1983) discussed a two-tier system of care with nurse practitioners in Rheumatology consulting in rooms next to Rheumatologists being "almost upon us". There was a general feeling that Rheumatologists would be threatened by the function of the nurses, taking over the education aspects of their role, however he does see some advantage in that the nurses:

> *"seem unlikely to supplant the surfeit of young doctors emerging from medical schools. They will complement them and leave doctors free to direct and co-ordinate treatment"* (Bird 1983 p 355).

The success of new drug therapies led to the reduction of Rheumatology inpatients and ward closures (Kjeken, Dagfinrud et al. 2006). Rheumatology became an outpatient speciality with the extra burden of additional clinics to provide the care, education and monitoring of patients on these therapies. It was therefore inevitable that the nursing role would expand to take on the consultation role and become an integral part of the Rheumatology Service.

2.7.2 Consultation models

Fundamental to deciding on which model to use for this thesis is to consider the aim of the consultation in which the model will be applied. The consultation model should consider those communication skills which are required to ensure that the aim of the interaction has been achieved. Therefore, the history of consultation models from the early work of Balint, through Pendleton and Neighbour to the Calgary Cambridge consultation model will be discussed. Whilst there are a number of consultation models which have been developed for different encounters, the models which will be discussed in this section are more

applicable to the process the nurse could apply when giving information to patients about Methotrexate.

2.7.3 The Development of Consultation Models

In order to understand the focus of this thesis on the Calgary Cambridge consultation model, a brief discussion of the early work of Balint, Pendleton and Neighbour will be discussed. These consultation models moved in the direction of the patient centred approach, and they had an important impact on the development of the Calgary Cambridge consultation model. Pawlikowska et al (2007) and Denness (2013) describe, among others, a number of patient centred consultation models which have varying key structures (Table 2.13).

TABLE 2. 12 CONSULTATION MODELS BASED ON PAWLIKOWSKA, LEACH ET AL. 2007 PAWLIKOWSKA, LEACH ET AL. AND DENNESS 2013

Model or Approach	Key Structure	Comments
Balint	Doctor/patient interaction	Attentive listening
Pendleton	Understand the problem and the patient Sharing of understanding, decision/responsibility	Patient centred/partnership model
Neighbour	Connect Summarise Hand over Safety netting Housekeeping	Patient centred
Calgary Cambridge	Initiate the session Gather the information Build the relationship Explain and plan Close the session	Patient centred and collaborative

The Balint model is based on the implication that both the doctor and the patient bring their own emotions into the consultation (Balint 1957). It does help the healthcare professional to think about those encounters; which can often leave them feeling emotional and physically drained (Denness 2013), but it is the beginnings of putting the patient at the centre of care. However Byrne and Long (1976) described a consultation process which very much kept the doctor in control (Table 2.14).

TABLE 2. 13 BYRNE AND LONG CONSULTATION PROCESS

Phase I	The doctor establishes a relationship with the patient
Phase II	The doctor attempts to discover the reason for the patient's attendance
Phase III	The doctor conducts a verbal and/or physical examination
Phase IV	the doctor or the doctor and patient or the patient (in that order of probability) consider the condition the patient presents with
Phase V	The doctor and occasionally the patient, detail further treatment and or investigations
Phase VI	The consultation is terminated, usually by the doctor

This model favours the paternalistic approach to consultations which was practiced widely during the 1970s (Hoving, Visser et al. 2010). Stott and Davies (1979) also favour a paternalistic approach to consultation style, however, they do introduce the concept of patient self-management. They describe four aspects to the consultation; the management of the presenting problem, which is key to the consultation as they consider that if this is not dealt with the patient will not be receptive to any other activities. The modification of help-seeking behaviours is then considered, which includes discussion on how to manage certain conditions themselves without the need to approach the doctor, for example, managing a sore throat at home. They then consider that reviewing current long-term healthcare

problems should be undertaken at the consultation, for example, reviewing a blood pressure and the final aspect of the consultation is around health promotion, ie taking this opportunity to discuss smoking cessation, or weight management with the patient. The Pendleton model further encourages the healthcare professional to involve the patient in the plan of care and to take some ownership of that process. It puts the patient at the centre of the consultation and encourages the individual to take some responsibility for their own disease management (Table 2.15).

TABLE 2. 14 PENDLETON'S SEVEN TASK CONSULTATION MODEL

1.	Define the reason for the patient's attendance, nature of the problem, patient's ideas, anxieties and expectations and effects of the problem on the patient
2.	Consider other problems and risk factors
3.	Choose an appropriate action for the problem with the patient
4.	Achieve a shared understanding with the patient
5.	Involve the patient in managing the problem and encourage them to accept responsibility
6.	Use time and resources appropriately
7.	Establish and maintain a positive relationship with the patient

Neighbour (2004) first published his book "The Inner Consultation" in 1987 and describes a five-stage model where he talks about connecting described as establishing a rapport. The model involves summarising what the patient has said, which aims to check that the healthcare professional has understood what the patient has come to see him for. Handover, at this stage the healthcare professional agrees a management plan with the patients, involving them in their care and agreeing areas where that patient can take responsibility. Safety netting, this is where a contingency plan is formed, just in case the diagnosis is incorrect. The final stage is housekeeping, which deals with any emotions or

issues; which could have arisen as a result of the consultation. This consultation is very patient-centred, but it lacks elements on how to end a consultation, which some healthcare professionals can find challenging.

(Kurtz and Silverman 1996) developed the Calgary Cambridge Referenced Observation Guides that identified the skills required to underpin the healthcare professional and patient communication. These guides were developed to be part of medical education in order to provide an evidence-based model, which can be applied to teaching skills required for the medical dialogue. However, it was not clear how to integrate these skills into the traditional approach to taking a medical history (Kurtz, Silverman et al. 2003). The guides cover how to determine the main problem of the patient; how to take a history of that problem and past medical history; how to determine family history; the recording of personal and social history; recording of drug and allergy history reviewing body systems and functioning. Kurtz, Silverman et al (2003) reviewed their guides and modified them to produce a more comprehensive framework for the application of the model. They produced diagrams in order to visually represent the concepts of the model. Figure 2.2 shows the basic framework, which maps not only communication but physical examination also.

FIGURE 2. 2 THE BASIC FRAMEWORK OF THE CALGARY CAMBRIDGE MODEL (KURTZ, SILVERMAN ET AL. 2003)

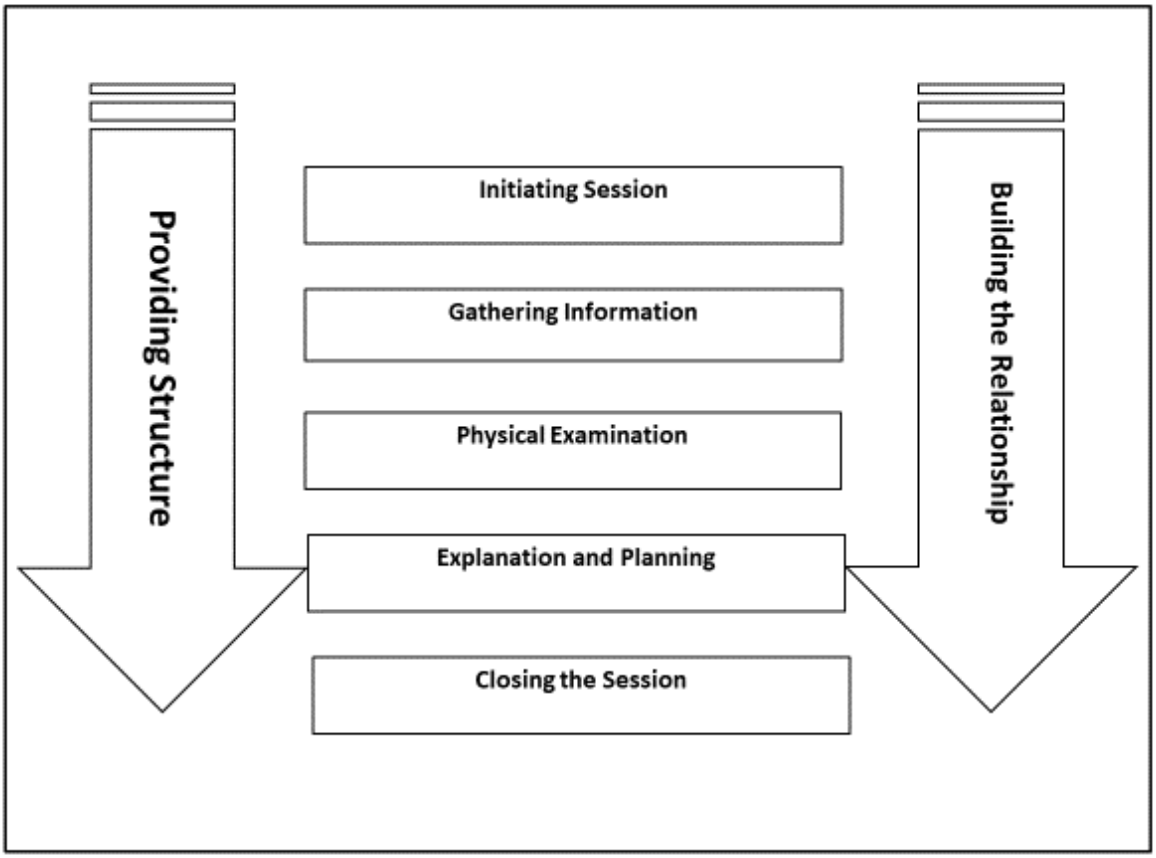
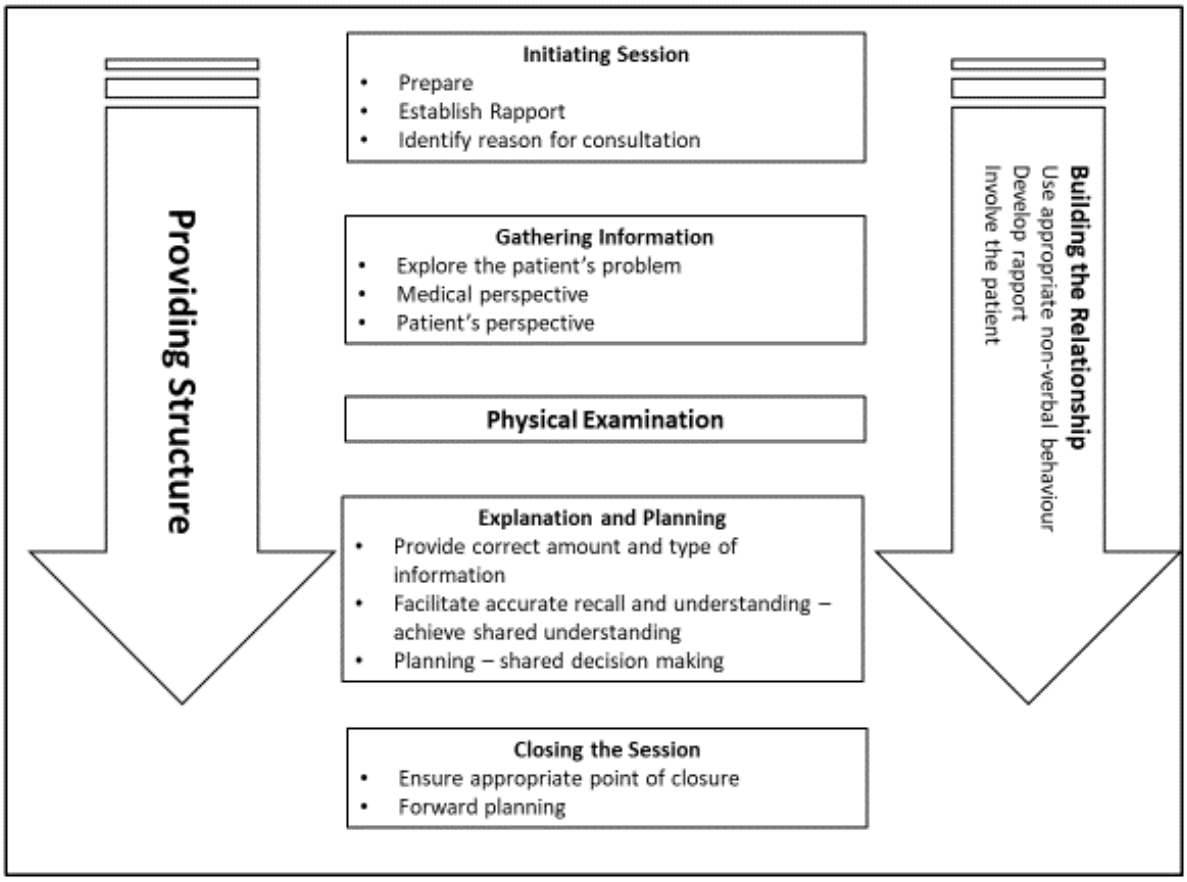


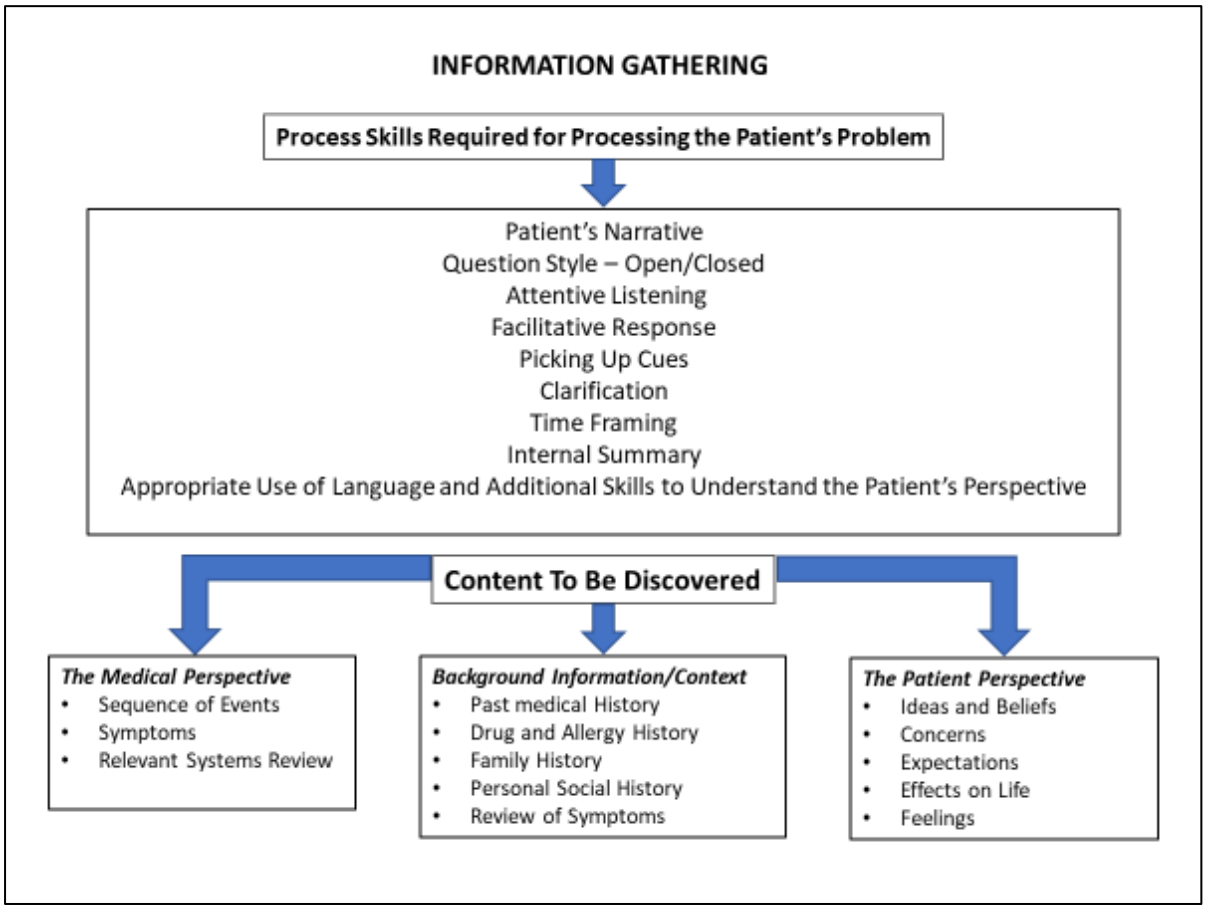
Figure 2.3 shows the expanded framework where Kurtz, Silverman et al (2003) have broken down the components of each of the communication elements in order to refine the conceptualization of the model in order that the healthcare professional can apply it to the consultation process.

FIGURE 2. 3 THE EXPANDED FRAMEWORK OF THE CALGARY CAMBRIDGE MODEL (KURTZ, SILVERMAN ET AL. 2003)



In Figure 2.4 Kurtz, Silverman et al (2003) have taken one element of the process, gathering information, and give an example of how the model is applied.

FIGURE 2. 4 GATHERING INFORMATION (KURTZ, SILVERMAN ET AL. 2003)



Whilst the Calgary Cambridge consultation model was originally developed for use in medical education, it has been adapted and used to provide a framework for other professional consultations (Greenhill, Anderson et al. 2011), and has even been adapted for use in veterinary practice (Adams and Kurtz 2006, Englar, Williams et al. 2016) which demonstrates its flexibility.

(Munson and Willcox 2007) argue that consultation skills are the most important skills required by a practice nurse in general practice. They identify that the core tasks of any consultation are to identify what the patient's main problems are and what worries that individual the most, then assess the impact this has on the physical and emotional well-being of that person and their family. They reviewed other consultation models but concluded that the Calgary Cambridge consultation model is the most appropriate to be

used by practice nurses as it complements the holistic approach already practiced by those healthcare professionals.

2.7.4 Relevance of Consultation Models to the Nurse-Patient Interaction

As previously discussed, a number of different consultation models have been developed for use in different settings, but the basic aim of the consultation is to uncover the issues, problems and symptoms a patient may have (Willcox and Munson 2007). Further the models have generally been aimed primarily at doctors (Harper and Ajao 2010) and therefore need to be adapted for the nursing role. The early models were paternalistic in their approach, but as medical beliefs changed, the focus of the consultation also changed.

The models are useful for doctors in the management of problems that the patient may present with; however, the focus of this thesis is how nurses give information on Methotrexate to patients and how they ensure that the patient understands that information. Therefore, the need to determine an underlying medical problem with the patient is not necessarily useful in that information giving interaction. The Calgary Cambridge consultation model, (Kurtz, Silverman et al. 2003) clarifies the consultation process in more detail and Table 2.16 shows how this could be applied in the Methotrexate information giving process a Rheumatology Specialist nurse will undertake.

TABLE 2. 15 THE NURSE CONSULTATION PROCESS BASED ON THE CALGARY CAMBRIDGE MODEL

The Calgary Cambridge Model	The Nurse Consultation
Initiate the Session Establish Rapport Involve the Patient	Initiate the Session Introductions – Nurse Patient Nurse orientates the patient
Gather Information Explore the problems Understand the patient's perspective Provide structure to the consultation	Gather Information Nurse gains an understanding from the patient why they are there Nurse establishes the patient's current knowledge Nurse explains how the consultation will proceed
Building the Relationship Develop a rapport Involve the patient	Building the Relationship The nurse asks the patient about their disease, how they feel and any other issues they may have Nurse introduced the concept of shared decision-making and patient self-management
Explanation and Planning Provide the correct amount and type of information Aid accurate recall and understanding Achieve a shared understanding Planning – shared decision-making	Explanation and Planning Nurse gives information about Methotrexate to the patient in small segments Nurse stops at each segment and discusses recall of the information with the patient, to ensure understanding Nurse observes verbal and non-verbal cues in this process Nurse makes decisions around relevant information to give each individual Decisions are made between the nurse and the patient regarding planning of follow up sessions

Thus, the Calgary Cambridge consultation model appears to be the most appropriate model and has the adaptability to apply to the consultation process between the nurse and the patient during the Methotrexate information giving encounter.

2.7.5 Skills required to conduct a Consultation

The following two sections will review the literature around those skills which are required to deliver a consultation and the current literature on how Rheumatology Specialist nurses conduct their consultations.

2.7.5.1 Communication and Interpersonal Skills

It is beyond the scope of this thesis to describe communication and all of its complexities; therefore, the focus will be on those skills that are necessary to conducting a consultation between a healthcare professional and patient during the process of giving information on drug treatment in Rheumatology.

Communication is a fundamental skill required by nurses across all of the settings of patient care; it is a cornerstone of practice and it is essential that nurses have the skills to understand the patient and the experiences they express and also to be comprehensible and acceptable (Kourkouta and Papathanasiou 2014). Communication is an inherent part of human nature but it is a complex interaction that occurs on many levels. There are many definitions of communication but in the context of this thesis it can be described as being "…about the reciprocal process in which messages are sent and received between two people" (Balzer–Riley 2004 p3). Communication, particularly in the context of a consultation, involves both verbal and non-verbal aspects (Ali 2018), the verbal aspect encompasses what is said or written. Tone, pitch, volume, pauses, fluency and speed of dialogue can have a conscious or unconscious impact on the meaning of those words. Non-verbal communication can relate to body language as demonstrated in Table 2.17.

TABLE 2. 16 EXAMPLES OF NON-VERBAL COMMUNICATION BASED ON ALI (2018)

Non-Verbal Communication	
Body Position	• Arms Folded/Open • Facing or turned away in relation to others • Head tilted or straight • Sitting/standing • Personal space
Facial Expression	• Smiling • Frowning • Eyebrows raised • Inexpressive
Eye Contact	• Avoidance • Maintaining • Writing • Reading • Uninterested
Touch	• Handshake • Pat on the back • Avoidance

Non-verbal as well as verbal communication can play an important role in healthcare professional and patient encounters (Vogel, Meyer et al. 2018). Those communication styles which demonstrate a closer connection with patients, relate to increased patient satisfaction than those with a more paternalistic style (Buller and Buller 1987, Stevenson, Barry et al. 2000). It is also important to consider that there could be cultural/personal differences that patients may have, which requires empathetic judgement. For example, touching someone could be offensive, and permission to do so should be considered. Some individuals may find eye contact uncomfortable, such as people with Asperger's (Ali, 2018). Thus, reading body language is a skill and could be regarded as being as important as observing clinical signs (Ali 2018).

Patients often exhibit cues indirectly rather than express openly their concerns (Butow, Brown et al. 2002), and it could be regarded that it should be a core skill of nurses to recognise these cues (Eide, Quera et al. 2004). Sheldon et al (2011) carried out an analysis of thirty-one randomly selected audio-recordings from an existing data set of oncology

visits. Their main goal was to observe patient cues of distress and the healthcare professional responses to those cues. They found that cues ranged from zero to 13 cues per visit and the healthcare professional acknowledged 57% of these cues, however they only explored 22% of the cues. Their conclusions were that the healthcare provider may have lacked knowledge, time and confidence in dealing with these cues, and recommended that education for the healthcare professional in managing cues could improve patient outcomes. Hall (2011) also considered that accuracy in interpreting cues is multi-layered. It is important to understand the healthcare professionals' cues in order to accurately decode the cues that the patient is responding to.

Charlton et al (2008) undertook a review of literature up to 2005, describing nurse practitioner/patient interactions in order to evaluate best practice. They identified two different styles in the literature; biomedical and biopsychosocial. The biomedical approach is authoritative and controlled focussing only on the signs and symptoms of the complaint. The biopsychosocial approach is person-centred that involved shared decision-making and ultimately empowering the patient to become part of the treatment pathway. This style had a much more positive influence on patient satisfaction, adherence to treatment options and overall patient health than the biomedical.

2.7.5.2 Rheumatology Nurse Consultations Skills

A number of studies have been conducted relating to Rheumatology nurse-led consultations. Hill et al (2003) carried out a randomised controlled trial with eighty people who had the diagnosis of Rheumatoid Arthritis. The study was designed to assess effectiveness of care in a nurse led Rheumatology clinic, the results of which indicated that there was a greater level of patient satisfaction with the nurse led clinic than the doctor led clinic, but the confounder here was that the doctors changed with their rotation every six months and therefore there was less consistency with who the patient saw. It was also not clear which consultation technique the nurses used, or whether indeed, they had been trained in any consultation method at all. Further, their main outcome measure was a disease activity score which remained stable in both groups. Therefore, it appears that

consultations skills had not been considered to have an important impact on the interaction between nurse and patient. Ryan et al (2006) hypothesised that a Rheumatology Specialist nurse would have a measurable impact on the well-being of patients with Rheumatoid Arthritis. They designed a single blinded randomized controlled trial to test this hypothesis. Seventy-one patients with Rheumatoid Arthritis who were starting a new DMARD, were recruited and randomised into two groups over a one-year period. One group was allocated to review by a Rheumatology Specialist nurse clinic, whilst the control group received the standard care of being seen by outpatient staff for their blood safety monitoring. The Rheumatology Specialist nurse further used Pendleton's consultation framework (Pendleton 1984) to assess patient needs as well as carrying out safety blood monitoring. Ten minutes were allocated to each consultation with the Rheumatology Specialist nurse and during this time, safety assessments were undertaken as well as assessment of pain, mood, and functionality. Furthermore, during this short consultation, advice was given on the use of analgesics, exercise and goal setting and referrals to other healthcare professionals such as physiotherapy and occupational therapy, was made if necessary. The results of the study showed that there was a significant improvement in disease activity in the group who had been seen by the Rheumatology Specialist nurse, which indicates that the nurse had a positive impact on disease outcomes for patients with Rheumatoid Arthritis. However, it is not clear how the consultation was actually structured and whether there was any shared decision-making in that process. The time allocated to the consultation suggests that the Pendleton consultation model was used to frame questions to explore other problems that the patient may have. Whilst this approach certainly benefitted the patient in comparison to the control group who had no intervention other than safety monitoring, it is unclear how far the patient was at the centre of the Rheumatology Specialist nurse consultation process.

The objective of a randomised controlled trial conducted by Koksvik et al (2013) was to determine patient satisfaction with nurse consultations in a Rheumatology outpatient clinic. 68 patients with inflammatory arthritis who had started a DMARD three months previously were randomised for their follow up to either a clinic led by a nurse or a clinic led by a doctor. The patients remained in their allocated groups for their three-month, nine-month and 21-month follow up appointments. Two Rheumatology Specialist nurses conducted the

visit in the nurse led clinics. Both had more than ten years' experience in Rheumatology and had undertaken Rheumatology courses at advanced level. This study was conducted in Norway. The patients saw the same nurse at each visit. Six doctors conducted the medical clinics and two of those were in their last year of training as Rheumatologists. There was no consistency with which doctor the patient saw at each visit timeline. Consultations for each lasted approximately 30 minutes. The primary outcome measure was patient satisfaction, assessed by the Leeds Satisfaction Questionnaire (Hill, Bird et al. 1992). The overall satisfaction rate was relatively high in both groups; mean scores were 3.96 (3.8 – 4.2) in the Rheumatology Specialist nurse group and 4.08 (3.9 – 4.2) in the doctors' group. However, there was a significant difference in satisfaction levels in the nine month and twenty-one month follow up appointments. Patients who had been seen by the doctors showed less satisfaction around the provision of information and access and continuity of care. This could reflect the lack of continuity of care in the doctors' group and the varying practices each doctor will exhibit. Whilst both nurses in this study had many years' experience in Rheumatology and had undertaken advanced level courses, it was not clear which consultation model they adopted. Indeed, assessment of the patient's disease status was carried out in a thematic check-list fashion. They did provide education and counselling which addressed self-management strategies, but there was no indication that a patient centred approach had been utilised, or what information was actually given and whether they checked to ensure the patient understood. The weakness of this study around comparing the nurses' consultation to the doctors' consultation is the lack of consistency. The nurses were able to establish a longer-term rapport with the patient, as they saw the same patient each time, whereas the doctors did not. Further the principal investigator was one of the Rheumatology Specialist nurses and her investment in the study may have had an impact on her performance.

The literature of the randomised controlled trials conducted around Rheumatology nurse consultations have been designed to test their effectiveness against doctors. Whilst this is important to justify the existence of nurse-led clinics, the literature is not specific in the description of the consultation processes Rheumatology Specialist nurses use. Larsson et al (2014) designed a randomised controlled trial to evaluate the effectiveness of a nurse led Rheumatology clinic compared to a Rheumatologist led clinic for patients undergoing

biologic therapy, where 107 patients were randomised to either standard care with the Rheumatologist consisting of a three-minute review appointment at six months and again at 12 months, or to be seen in a nurse clinic at six months. Thereafter at 12 months the patients would be followed up by the Rheumatologist as per standard care. The nurse intervention consisted of using a patient-centred approach, the purpose of which was to give the patient the opportunity to talk about themselves and their illness, leading to greater patient empowerment and self-management. Nevertheless, it was not clear how this was done and whether any particular consultation models were adopted. The authors concluded that the disease activity score did not significantly change, therefore replacing the six-month review appointment with a nurse clinic rather than a Rheumatologist clinic was safe and effective. This study does attempt to put the patient at the centre of care, but exactly how this was done is not clear.

Ndosi et al (2014) took a different approach to justify the value of a nurse led clinic by considering the cost-effectiveness of Rheumatology Specialist nurses. They designed a multi-centred randomised controlled trial to explore their objective and recruited 181 patients with Rheumatoid Arthritis to be randomised to either a nurse clinic or a Rheumatologist clinic. Again, the primary outcome measure was the disease activity score which was assessed at weeks 13, 26, 39 and 52. The authors describe a "holistic approach" adopted by the nurse clinic which involves taking account of patients' physical, psychological, social and spiritual needs, yet there was no description of how nurses were trained to provide this consultation model in the different centres where the trial took place, therefore the overall consistency of the nurse led clinics may be questionable. Further, the nurses had 30 minutes in which to conduct their clinics, whereas the Rheumatologists only had 15 minutes. The authors also highlight that in the follow-up period the proportion of patients receiving biologic drug treatments remained fairly constant in the nurse led clinics, whilst it doubled in the Rheumatologist clinics. This may reflect that Rheumatologists are often the decision makers when prescribing biologic therapies for patients, and it could even indicate that drug changes were missed by the nurse-led clinics leading to less than optimal treatment for the patients.

A systematic review was carried out by Garner et al (2017), the aim of which was to assess the quality of care for patients with Rheumatoid Arthritis, in nurse-led clinics. They

reviewed the literature to identify measures of quality of care used as outcomes in each study and calculated the number of studies reporting superior, equal and inferior results for nurse-led clinics with the comparator. Seventeen articles were selected; however, the inclusion criteria were not reported. They mapped out the outcome measures against six dimensions: effectiveness, acceptability, efficiency, safety, appropriateness and accessibility. Whilst they reported that nurse-led clinics were safe and were supported by patient outcomes such as satisfaction, coping and functional status, they noted that evidence in some dimensions such as efficiency, appropriateness and accessibility as under-represented. These dimensions related to cost-effectiveness, relationship with the care provider such as holistic care and provision of information and continuity of care. They concluded that further work needs to be undertaken to address these gaps in the research.

2.8 Chapter Summary

It is clear that Rheumatoid Arthritis is a debilitating disease which requires careful management and treatment. Some drug therapies such as Methotrexate can occasionally have harmful side effects; therefore, it is of the utmost importance that the patient understands how to take the drug safely, understand warning signs of side effects and to take the drug as prescribed. It is a part of the role of the Rheumatology Specialist nurse to advise the patient on the management and administration of this drug, in order for the patient to make informed decisions and choices about their own treatment. It remains unclear following this literature review, how nurses are trained to give this information, and how deep their knowledge of drugs such as Methotrexate is.

An examination of the literature on nurse consultations reveals that it primarily focusses on the comparison of the nurse with a Rheumatologist undertaking consultations, perhaps with the aim of justifying nurses in this role. However, what is not clear is how those nurses were trained to carry out their consultations and how effective their technique was. Further, it is unclear how the practice of shared decision-making underpins the nurse consultation process. The majority of papers and articles relating to specific drug therapies for the treatment of Rheumatoid Arthritis revealed that the decisions were made by the clinician

without consultation with the patient. It is clear from this literature search that although there is a growing awareness of the value of patient involvement in their care pathway, it is relatively under-represented in the literature. Therefore, the quality of the interaction between nurse and patient on knowledge gained as a result of that interaction is understated in the literature. Whilst it can be seen that nurses have a major impact on the Rheumatology services delivered throughout the world, there is little evidence available on what skills are required and how those skills are achieved. It is also clear that there is a lack of demonstrable standardization for specialist nurse training in many treatment areas (Ranchal, Jolley et al. 2015).

2.9 Aims and Objectives

The literature review has revealed gaps regarding how nurses gained knowledge about consulting with patients and how they delivered that information using consultation techniques which has contributed to the formation of the aims and objectives of this thesis. The overall research question was how do Rheumatology Specialist nurses gain knowledge about consulting with patients on Methotrexate and do they deliver the information to patients using a consultation technique, further can elements of their consultation be identified for development? This was investigated by:

- Investigating, using a survey, the processes which nurses undertake to become knowledgeable about consulting with patients on Methotrexate and to understand how much knowledge and confidence they have in giving this information.

- Exploring, through semi-structured interviews, the nurse experience and perception of the delivery of information about Methotrexate to patients.

- Identifying, through video analysis of consultations, the processes used by the nurses in their consultations with patients when giving information about Methotrexate and

how the consultations may be further developed using the Calgary Cambridge consultation model.

Chapter 3: Methodology

3.1 Introduction

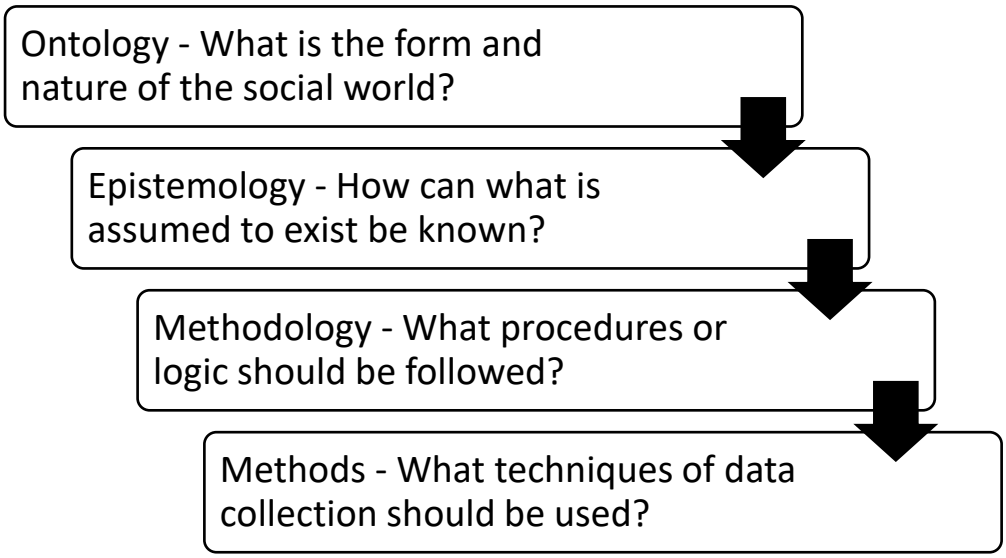
Slevitch (2011) describes several fundamental terms used in the philosophy of science and research and explains that a paradigm can be defined as a 'world view' or set of assumptions about the world as well as a cognitive process or the shared beliefs of a particular discipline. These paradigms are determined by the ontological perspective which describe what exists or is believed to exist and the existence of relationships between different phenomena. The ontological dimension then establishes the epistemological position which is concerned with the theory of knowledge. This then leads to the next term, methodology, which is based on a system of theories. Each methodology specifies the assumptions about reality and human nature, beliefs about what is important to research and assumptions about what establishes legitimate knowledge and meaningful data. Each methodology then leads to the creation of methods which are the tools, procedures and techniques to be employed in the scientific enquiry (Smith and Heshusius 1986). Hughes and Sharrock (2007) further describe "method" and "methodology" as two different aspects of research practice. Method refers to those procedures and practices which are involved in collecting the research data, whereas methodology refers to the underpinning rationality and justification of those particular methods.

This chapter will discuss the ontological and epistemological paradigms which underpinned this thesis and how these paradigms influenced the methodological perspective of this work. This chapter will also discuss the methods which were applied to this mixed methods research thesis to explore how nurses gained knowledge about consulting with patients on Methotrexate. This thesis sought to explore how they delivered that information to patients and to identify elements of their consultation for further development. Both qualitative and quantitative data were collected through a national questionnaire survey, semi-structured interviews and video-recordings of the nurse-patient consultation, to obtain overall context and a richer, more in-depth perspective, therefore further discussion of qualitative and quantitative research methods will be conducted. The philosophy which underpins this thesis is critical realism, and will be discussed later in this chapter.

3.2 Ontological and Epistemological Perspective

Research is framed by a series of related assumptions (Arthur 2012) and these can be outlined around four questions; what is the form and nature of the social world, how can what is assumed to exist be known, what procedures or logic should be followed, and what techniques of data collection should be used (Figure 3.1).

FIGURE 3. 1 THE RELATIONSHIP BETWEEN ONTOLOGY, EPISTEMOLOGY, METHODOLOGY AND METHODS (ARTHUR 2012)

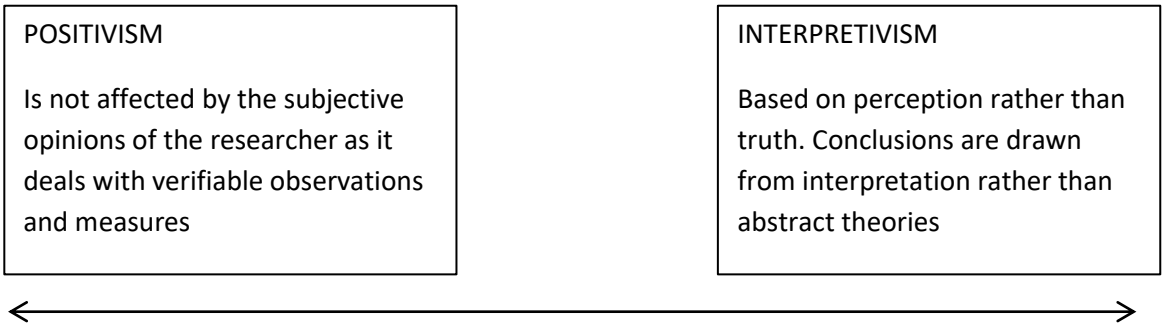


Ontology, as a branch of philosophy, is the science of what is being, existence, identity, processes and relations in every area of reality (Gruber 2018). Ontological perspectives can be viewed as a single line, from realism to constructivism. From the realism perspective there is one single reality which exists independent of individual perception whilst at the other end of the continuum constructivism represents realities which are constructed by the individual (Figure 3.2).

FIGURE 3. 2 ONTOLOGICAL PERSPECTIVES BASED ON ARTHUR (ARTHUR 2012)

The ontological perspective of the research forms the base on which to determine the epistemological viewpoint. The second question that Arthur (2012) poses refers to the epistemological position and relates to knowledge. From a positivist position it is possible to gain direct knowledge of the word through observation or measurement of the phenomenon. But the other extreme is an interpretivist belief where it is not possible to gain direct knowledge and that knowledge is developed through a process of interpretations of the world (Figure 3.3).

FIGURE 3. 3 EPISTEMOLOGICAL PERSPECTIVES BASED ON (VANSON 2020)



Easterby-Smith et al (2012) summarise the differences between these two concepts. In the strongly positivist position, the researcher has to discover the laws and theories to explain reality which is undertaken through experimentation and precise measurements. But a less positivist position accepts that reality cannot be directly accessed and therefore the nature of this reality can be achieved through other methods, such as conducting surveys. The interpretivist perspective follows that the researcher needs to collect multiple perspectives through quantitative and qualitative methods to gather the views and experiences of individuals (Table 3.1).

TABLE 3. 1 DIFFERENCES BETWEEN POSITIVISM AND INTERPRETIVISM (EASTERBY-SMITH, THORPE ET AL. 2012)

	POSITIVISM	INTERPRETIVISM
Basic Beliefs	The world is external and objective The observer is independent Science is value free	The world is socially constructed and subjective Observer is part of what is observed Science is driven by human interest
Researcher should	Focus on facts Look for causality and fundamental laws Reduce phenomena to simplest elements Formulate hypotheses and then test	Focus on meanings Try to understand what is happening Look at totality of each situation Develop ideas through stimulation from data
Preferred methods include	Operationalizing concepts so they can be measured Taking large samples	Using multiple methods to establish different views Small samples investigated in depth or over time

The aim of this thesis was to examine how Rheumatology Specialist nurses gain information on how to conduct consultations with patients giving information about Methotrexate. The objectives were to design a national survey exploring how they become knowledgeable, to conduct semi-structured interviews to gather the views and experiences of those nurses conducting the consultations and to analyse in detail video-recordings of the Rheumatology nurse-patient consultation in order to understand the reality of this phenomenon. This interpretivist perspective considers the multiple layers of investigation required in order to reach an understanding of the phenomenon under study. Furthermore the interpretivist perspective allows and recognises that the researcher is not separate from the investigatory process and acknowledges that theories which apply to their research was also relevant to themselves (Easterby-Smith, Thorpe et al. 2012). Whilst the interpretivist paradigm generally uses qualitative methods, a pragmatic approach to the paradigm provides the platform in which to utilise multiple research methods (Cresswell 2003). Table 3.2 describes how these

methods can cross boundaries, thus suggesting that the paradigm and research question determines the method of data collection and analysis which is most appropriate for the research question (Mackenzie and Knipe 2006).

TABLE 3. 2 PARADIGMS METHODS AND DATA COLLECTION (MACKENZIE AND KNIPE 2006)

Paradigm	Methods	Data Collection
Positivist/Postpositivist	Tendency towards Quantitative Methods	Experiments Quasi-experiments Tests Scales
Interpretivist/Constructivist	Qualitative Methods Predominantly	Interviews Observations Document reviews Visual data analysis
Transformative	Qualitative and Mixed Methods	Diverse range of tools
Pragmatic	Qualitative and/or Quantitative Methods	Tools from Positivist and Interpretivist paradigms

3.2.1 The Positivist Paradigm

This term was coined by Auguste Comte, a French philosopher who believed reality could be observed and that all genuine knowledge can only be advanced by observation and experiment (Mack 2010). Mack further explains that the ontological assumptions of positivism maintain that reality is external to the researcher and this reality is represented by objects in space which have an independent unconscious meaning. The epistemological assumptions maintain that truth can be reached because knowledge is objective and based on firm unquestionable truths from which beliefs can be comprehended. This paradigm generally uses quantitative methodology and scientific experimentation, thus the researcher is external to the phenomenon and controls the research process (Taylor and Medina 2011). Post-positivism however, allows for more interaction between the researcher and the phenomenon (Willis, Jost et al. 2007). Post-positivism methods include surveys, interviewing and participant observation (Cresswell 2008).

3.3 The Interpretivist Paradigm

The core belief of the interpretivist paradigm is that reality is socially constructed (Thanh and Thanh 2015) and is more concerned with the in-depth variables and factors related to a situation (Alharahsheh and Pius 2020). The ontological position of interpretivism is relativism, or the view that reality is subjective and differs from person to person (Guba and Lincoln 1994). Scotland (2012) further comments that reality is individually constructed, therefore there are as many realities as individuals. From an epistemological position knowledge is based on real world phenomenon where individuals construct meanings in different ways but through communication with other people and perhaps for practical reasons, a consensus is reached to share the same ideas (Pring 2000). To illustrate the differences between these paradigms, Taylor and Medina (2011) offer three analogies to describe positivism, post-positivism and interpretivism:

> "A positivist fisherman stands on a riverbank and describes the social properties of a species of fish by observing the general tendency of their group behaviour as they swim around".
>
> "A post-positivist fisherman supplements his quantitative observations of the social properties of a species of fish by wearing a wetsuit and conducting structured interviews of a random sample of fish to ascertain their reasons for swimming in accordance with the inferred social pattern".
>
> "The interpretive fisherman enters the water, establishes a rapport with the fish, and swims with them, striving to understand their experience of being in the water".

Coe (2012) considers that the whole notion of a paradigm is problematic. Whilst he describes a simplistic view of opposing paradigms in Table 3.3 there are always inconsistencies which are treated as puzzles to be worked out. But occasionally those inconsistencies lead to such significant anomalies that they trigger a new paradigm which cannot be measured against the old paradigm as it offers a completely different way of viewing the world.

TABLE 3. 3 OPPOSING VIEWS OR PARADIGMS (COE 2012)

The world and phenomena are real and to exist independently of perception	Social phenomena are always perceived in a particular way: they have no reality independent of perception
There is truth and objective knowledge about the world	Individual social contexts are unique: generalisation is neither desirable nor possible
Research should aim to discover general (generalizable explanations for phenomena to make generalizable predictions	Research should aim to understand individual cases and situations and to focus on the meaning that different actors bring to them
The kinds of objective knowledge and facts discovered by research are not dependent on the values and beliefs of particular researchers	Understanding the values and beliefs of researchers is crucial to understanding their claims
Power relationships are not relevant to the truth	Power and particularly imbalances of power, are central to understanding social phenomena. A key purpose of research is to emancipate and transform
Research aims to develop and test hypotheses. Hypotheses must be clearly stated before a study can be designed to test them	Research is inductive, following an unending dialectical cycle of thesis, antithesis, synthesis. Hypotheses and theory emerge in the course of researching; they are critically tested and refined against data and theory. Researchers aim to avoid making assumptions before collecting data
The world is fundamentally mechanistic and deterministic, in which human behaviour is governed by general laws and is capable of manipulation	Human beings are active participants in the researched world, interacting with rather than reacting to their environment, constructing situations by bringing their own meanings and acting freely
Phenomena can be understood by analysis of their component parts (reductionist)	Social phenomena are more than the sum of their parts and can be understood only holistically
Constructs must be operationalized to be used in research. Many constructs can be quantified and treated as having measurement properties. Characteristics such as validity and reliability are crucial	Many constructs cannot usefully be quantified; only rich qualitative description can capture their essence. Representations of phenomena must be authentic, based on studying things in their natural settings
Generalisation from observed samples is justified in terms of statistical representativeness and probability sampling	Observed cases can be a basis for generalizable theory and understandings, even where the number of cases is small (perhaps even one) and they are selected for some particular characteristic
Quantitative	Qualitative

The next section of this chapter describes the underpinning philosophy of this study which emerged through the construction and integration of the mixed methods design required to

explore the research question. The relationship between the underpinning philosophy and the mixed method design will then be discussed. The final sections will then describe the methodologies which underpin each of the three phases of this study.

3.4 The Philosophy of Critical Realism

All individuals have their own understandings and beliefs about the world in which they work and live (Proctor 1998). They have their own thoughts about what amounts to, for example, good healthcare, what they think is right or wrong about a particular situation, and whether they think that someone could do a task in a better way. These can be described as personal paradigms or personal philosophies (Proctor 1998) and illumination of these beliefs can contribute to perceptions between the ontological/epistemological/methodological interactions at the very planning stage of a study. Understanding the philosophical underpinnings of a study clarifies the concepts behind the methodological processes of that study (Appleton and King 2002). The aim of this thesis was to examine how Rheumatology Specialist nurses gained knowledge about consulting with patients on Methotrexate and how they delivered that information to patients. Therefore, it could be argued that it is not enough just to understand the existence of the fact that Rheumatology Specialist nurses give information about Methotrexate to patients, but to explore and gain an understanding of the underlying reality, or more specifically how the nurses gain their knowledge to carry out consultations with patients, which identifies critical realism as the philosophy underpinning this thesis. A clear understanding of the philosophical underpinnings of the research strategy helps to ensure consistency when applying different methods to a research question. This provides the foundation for the research methods within the epistemological paradigm and appraise the research design (Proctor 1998).

3.4.1 Critical Realism and Overview of the Key Literature

The origins of critical realism lie in a series of books by Roy Bhaskar and Margaret Archer (Archer, Bhaskar et al. 2013, Vincent and O'Mahoney 2018) in which it is argued that the universe is “a stratified and open system of emergent entities”. Entities can be described as those things which make a difference in their own right (Fleetwood 2005). For example a

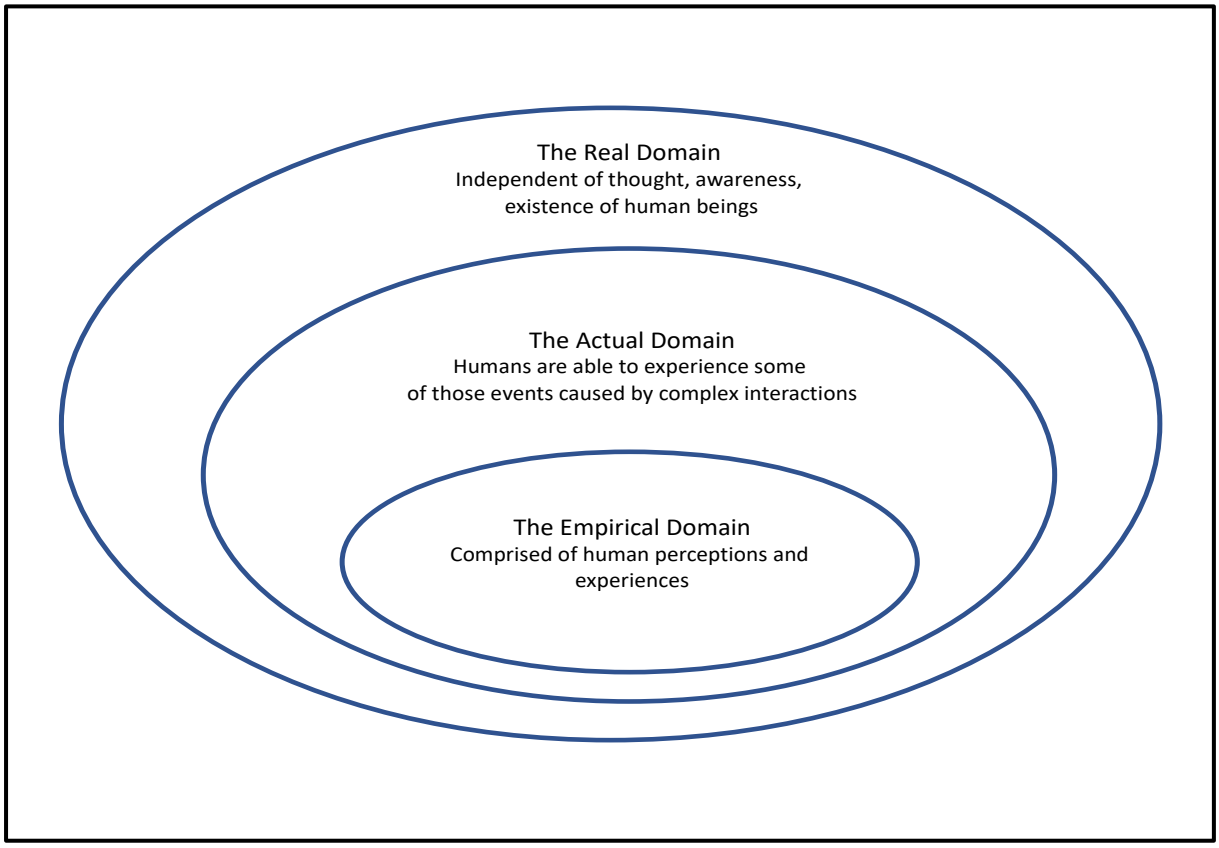
molecule of water is made up two hydrogen atoms and one oxygen atom; seperately these entities are unobservable to the naked eye, but by interacting they become observable as water, this then is an emergent property of hydrogen and oxygen (Cruickshank 2012). Therefore, Bhaskar's (2013) proposition is that the world is an open stratified system because unobservable underlying laws interact in subjective ways resulting in observable change.

Bhaskar was influenced by his tutor Rom Harre who laid the foundations of critical realism with his criticism of positivism and believed that there must be underlying propagative mechanisms in order to explain the world in terms of cause and effect (Danermark 2019). Also Mario Bunge argued in 1979 and 1993 that reality was arranged in levels, and that there was a distinction between the real world and the conceptual one (Danermark 2019). Danermark (2019) describe several distinct stages in the development of critical realism. The first stage is generally known as "basic critical realism" which was originally termed "transcendental realism" by Bhaskar (1989). This phase saw the introduction of underlying laws, the structure of the world and distinctions between beliefs and being, the aim of this phase was to develop a new logic of scientific discovery. The next stage is known as "dialectical critical realism" in which Bhaskar developed a more philosophically robust understanding of change, as reality is constantly in a process of change and whilst Bhaskar was aware of this from the beginning of his development of critical realism, it still took him about ten years to develop (Danermark 2019). During this time, he also became aware of the importance of "absence" which gives rise to a want or relieving of a need, in which process, negation and transformation are key concepts. This dialectical, or logical reasoning stage, has an important function in social research. The third stage of the development of critical realism as explained by Danermark is the "meta-reality" phase. This phase has a more reflexive focus; it looks to the inner or empirical world.

Bhaskar challenged the traditional view of scientific research which emphasized the belief that truth lies with firm law-like observations for phenomena (Clark, Lissel et al. 2008). He believed that this approach to truth was problematic as knowledge also lies in the social domain as social process and could be seen as relative to the individuals themselves. There was little clarity on who or what could determine truth and indeed, what truth was. Critical realism,

therefore, looks to understand the beliefs held by people and how those beliefs interact with external influences such as culture, gender and cultural attitudes (Proctor 1998) where reality is stratified into three domains (Figure 3.4).

FIGURE 3. 4 THREE DOMAINS OF REALITY



The first layer is the real domain and is described by Schiller (2016) being independent of thought, awareness and even the existence of human beings. Schiller considers that it is important to understand that whilst the real domain may not be detectable or observable by humans it does not make any less present in the critical realist viewpoint. Fletcher (2017) describes the second level, actual, where there is no filter of human experiences, and events occur even though they may not be witnessed by a person. Therefore, the actual domain includes all those events and phenomena that have been generated in the world regardless of whether they have been experienced by an individual or not and this is because not everything in the world can be observed (Schiller 2016). The final layer is the empirical domain where events or objects can be measured through the human experience or interpretation,

often called common sense (Fletcher 2017). This is the level of reality where social ideas, meanings and actions occur, where new empirical and non-empirical knowledge is generated through researcher endeavours and the creation of theories regarding natural and social phenomenon (Danermark 2019).

Williams (2007) considers that sensory knowledge is the cumulative knowledge that is learned from sight, sound, touch, movement, smell and taste which provides a level of evidence that can be challenged. It also includes a range of sensory experiences including hunger, thirst, pain, fright etc. This is classified as “empirical” knowledge. Non empirical knowledge is that knowledge which is independent of the sensory experience (Williams 2007). Human social processes and perceptions are imperfect therefore beliefs are not necessarily equal to objective truth (Clark, Lissel et al. 2008). Examination of these beliefs should consequently be deduced with reference to other available data or arguments. For example, if a person with an incurable chronic disease believes that they will one day be cured of that disease, from a Critical Realism perspective it can be considered that that patient is wrong, based on the evidence and knowledge that is available. Epistemologically, it can be considered that the patient is wrong, therefore the perspectives of the patient and professionals have been considered in conjunction with the available evidence and knowledge, arriving at an acknowledgement of the value of the different and reliable sources of evidence which relate to that phenomena (Clark, Lissel et al. 2008). Ryan (2019) describes the philosophical principles of critical reality (Table 3.4).

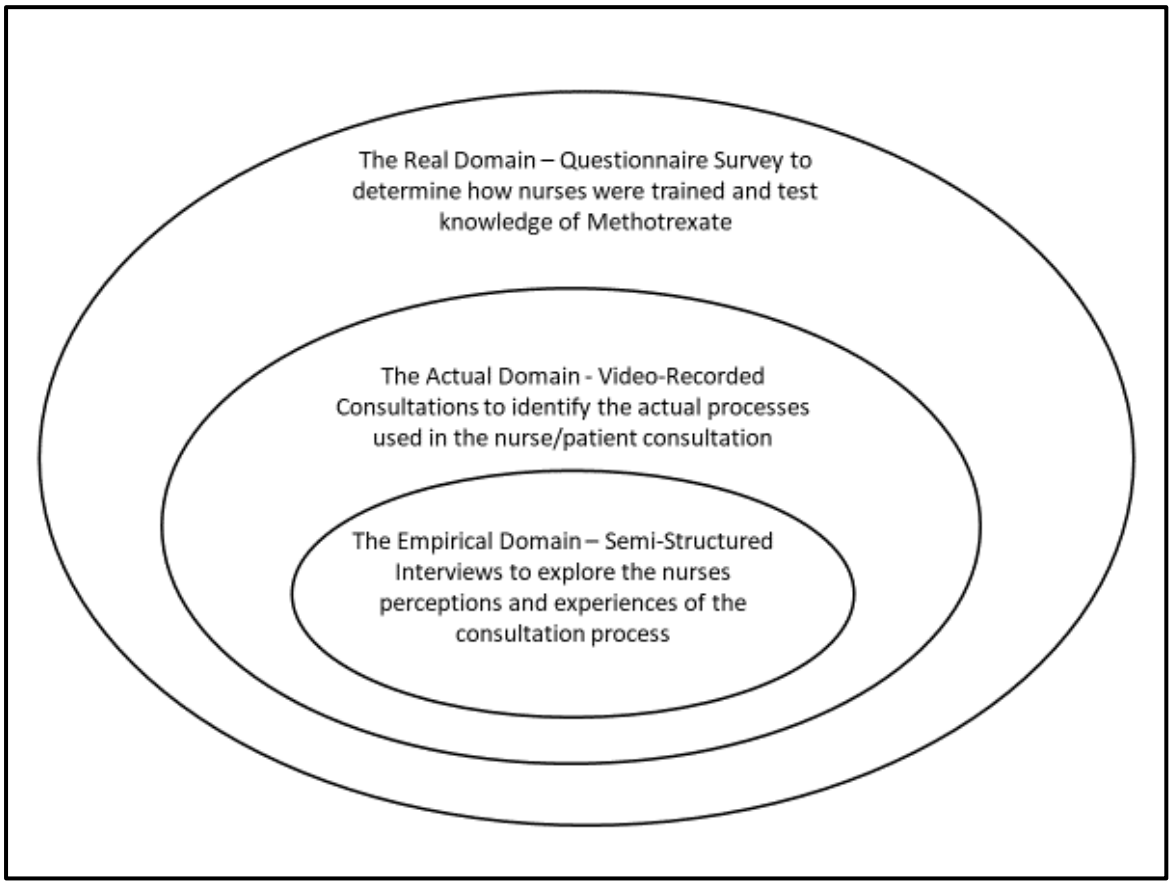
TABLE 3. 4 THE PRINCIPLES OF CRITICAL REALISM (RYAN AND RUTTY 2019)

Critical Realism
➢ There is one reality, never completely known, but can be seen differently from different perspectives. What is observed, felt, measured or analysed are only representations of this reality
➢ Reality can be viewed and interpreted by different people in different ways but it is still one single reality viewed from different perspectives (modified reality)
➢ Social systems are complex and changing, therefore they cannot be controlled and free from bias
➢ Knowledge evolves and progresses and can change over time
➢ What could be a fact in one situation may not be in another
➢ Knowledge should be generated through a range of sources and methods which uses theoretical frameworks, previous knowledge, research and the collection of data
➢ Knowledge should be fit for purpose ie it should be accessible, applicable, usable and relevant

Criticial Realism assumes that an ontological theory leads to an epistemological theory (Scott 2005). In other words, theorising on what is real, will lead to what is true. Scott puts forward two propositions; that empirical research methods needs to be underpinned by a meta-theory or an overarching theory or philosphy, such as empiricism or critical realism. Even though a researcher may not specifically address the philosophical issues, because they engage with the real world providing a explanation of it, those philosophical issues underpinn the methodological decisions which are made (Scott 2005). The second proposition Soctt puts forward is; believing that an independent reality exists and does not necessarily mean that deeming absolute knowledge of that reality is the only way it will work.

The application of Critical Realism underpinning this thesis is demonstrated in Figure 3.5.

FIGURE 3. 5 THE PHILOSOPHY OF CRITICAL REALISM UNDERPINNING THIS THESIS



It could be argued that when an individual completes a questionnaire survey they complete it to the best of their knowledge and beliefs at that time, but what is real to them may not be what is observed. Therefore in designing this thesis, further layers of investigation were required to observe different perspectives of the same reality. Semi-structured interviews allow for a more in-depth exploration of what is real to the individual, but again, there is a subjective element in that the individual's beliefs could influence the interview and their perception of the truth. The third layer, video-recording, allows the researcher to view the world from a very different perspective. However, a rigorous analytical approach to reviewing the data from the video-recording, is essential, as the researcher's own beliefs and truths could influence the outcome. Bhaskar's view that the world is an open stratified system (Bhaskar 2013) where unobservable laws can cause observable change, underpins the chosen methodologies for this thesis. The aim of this study was to observe and understand those beliefs and events which result in current practice when undertaking consultations and shape the way that Rheumatology Specialist nurses undertake

Methotrexate education today. The next section in this chapter will examine the literature to understand how critical realism aligns itself with a mixed methods research approach.

3.4.2 The Fusion of Critical Realism and Mixed Methods Research

Shannon-Baker (2016) views mixed methods research as the type of enquiry which has philosophical foundations, where there is an intentional use of both qualitative and quantitative research methods in one single study. This results in a richer understanding of that phenomenon than using one method alone and this is echoed by other writers such as Cresswell (2015). Maxwell and Mittapalli (2010) consider the application of critical realism to mixed methods research and consider its appropriateness to this approach. They consider that by taking a critical realism approach, the research design can be viewed as real entities and not simply "models" for that research question. That critical realism allows real concepts and practices to shape the study design, rather than reconstructing the logic or hypothesis from the inquiry process, "reconstructed logic" (Kaplan 1973). Kaplan's definition of -logic-in-use are the on-going thought processes which govern scientific investigation whereas reconstructed logic are those processes which are propagated after the fact and could in fact be substantially different to logic-in-use. Maxwell and Mittapalli (2010) also consider that the critical realism philosophy allows the reflexive position of the researcher and stakeholders to contribute a meaningful component to the design of the study. Within the qualitative research approach, this reflexive position confirms that the researcher is part of the data collection process and that conscious or unconscious preferences may affect or contribute to the process (Ormston, Spencer et al. 2014). Therefore the adoption of a reflexive position on the design of a study could allow the researcher to identify potential preconceptions which may affect the processes of data collection and the data itself (Ritchie, Lewis et al. 2013). A reflexive account of the researcher's perspective will be described at the end of this chapter in section 3.10.

A critical realism approach undertakes to probe into deeper levels of understanding, investigating multiple viewpoints (McEvoy and Richards 2006) and it could be considered that within the same reality the three ontological domains of the empirical, the actual and the real, can be inferred by combining empirical investigation and theory construction. From a critical

realism perspective, the choice of research method should be dictated by the research question and in many cases, this could be implemented by using both quantitative and qualitative methods. Quantitative methods provide reliable descriptions and accurate comparisons, whilst qualitative methods can reveal patterns and associations which may not necessarily be obvious (McEvoy and Richards 2006) Thus the first objective of this thesis; to investigate the processes which nurses undertake to become knowledgeable about the consulting with patients to give information about Methotrexate, was undertaken using a survey to provide quantitative data to produce accurate descriptions and comparisons. The second objective exploring the experiences and perceptions of nurses in the delivery of information about Methotrexate was undertaken through semi-structured interviews and the third objective; to identify how the nurse patient consultations could be further developed was undertaken through video-analysis. These approaches embraced qualitative methods which as McEvoy and Richards (2006) point out that a key advantage of these methods is that they are open ended from a critical realism perspective, this allows themes to emerge which may not necessarily have been anticipated. Thus, this study design was based on a mixed methods approach with an underpinning critical realism philosophy.

3.5 Mixed Methods Research

The following two sections will review the literature concerning the development and application of mixed methods research and the debate around adopting this approach.

3.5.1 The History of Mixed Methods Research

There is a general view that mixed methods research established its beginnings in the 1950s (McKim 2017), however, Johnson et al (2007) position the beginnings of mixed methodology back to Plato and the Sophists. Debates on understanding the world and the philosophical truth of everything goes back to Socrates and Plato who argues for multiple truths as opposed to relative truths as proposed by the Sophists, Protagoras and Gorgias. Johnson et al argue that these deliberations continue to affect how knowledge and truth are considered and that the divergent views of Plato and the Sophists could be regarded within a mixed methods context in order to determine a solution that covers multiple viewpoints.

In its more recent history, mixed methods emerged because researchers considered that both the qualitative and quantitative perspective could be adopted in order to examine their research questions (Johnson, Onwuegbuzie et al. 2007). However, as early as the 1920's mixed methods approaches to inquiry were being adopted (Lynd and Lynd 1937). Lynd and Lynd conducted a complete survey of a small midwestern city in North America and in 1931 Jahoda et al (2002) carried out a survey of a town called Marienthal in Austria. Whilst their methodologies were not robust and generally developed as the projects developed, these studies applied mixed methodology, using for example official statistical information, interviews and psychological tests.

3.5.2 The Mixed Methods Debate

In 1959 Campbell and Fiske developed a technique which measured two traits by, at the minimum, two different methods, they termed this the "multi-trait multimethod technique" (Campbell and Fiske 1959). Validity is measured by correlation of the values of the different methods and should be high enough to reflect convergent validity or common trait variance (Lowe and Ryan-Wenger 1992). The work by Campbell and Fiske has been considered the beginnings of mixed methods research (Maxwell 2016). However, the 1980s and 90s witnessed considerable dispute around mixing qualitative and quantitative methods for research revealing purists on both sides (Johnson and Onwuegbuzie 2004). Quantitative purists argued that social observations should be viewed as a scientific enquiry, where the observer is separate from the objects under study and objectivity should be maintained consequentially producing outcomes which are reliable and valid (Nagel 1989). On the other hand, qualitative purists would argue that there are numerous realities and that cause and effect are interlinked. So it would be impossible to separate and differentiate between them as knowledge is generated inductively from the resulting data (Johnson and Onwuegbuzie 2004). Further, the data collection methods differ between the two paradigms as quantitative data collection tends to be highly structured and organised using large samples sizes, whereas qualitative data collection involved exploring and recording individual perspectives and experiences which often involve smaller sample sizes. These two opposing viewpoints are summarised in Table 3.5.

TABLE 3. 5 SUMMARY OF THE DICHOTOMY BETWEEN QUANTITATIVE AND QUALITATIVE PARADIGMS BASED ON SALE ET AL.(2002)

Paradigm	Quantitative (Positivism)	Qualitative (Interpretivism)
Description	One Truth Objective Exists independent of human perception Cannot be influenced by the Investigator "one-way mirror"	Multiple truths Subjective Socially constructed and always changing Humans are an intrinsic part of that reality Investigator interacts with object of study Findings created within the context of the study shaping the inquiry
Techniques	Randomisation Blinding Highly Structured Protocols Questionnaires with limited closed answers	In-depth interviews Focus groups Participant observation
Sample Size	Large	Small purposeful, not meant to be representative of large populations

Sale, Lohfeld et al. (2002) go on to describe differences in the language which is used in these two paradigms which go beyond the philosophical and methodological debates. Quantitative language describes what is real out in the world and is an accurate reflection of this reality, whereas the language of qualitative research describes an interpretation of an individual or individuals' reality summarised in Table 3.6.

TABLE 3. 6 DIFFERENCES IN LANGUAGE USE IN QUANTITATIVE AND QUALITATIVE PARADIGMS

Language Example	Quantitative Meaning	Qualitative Meaning
Observational Work	Case control studies	Ethnographic emersion
Validity	Results agree with what is out there in the world	An interpretation or description with which one agrees
Research has shown…	An accurate reflection of reality	An interpretation which becomes reality

The basic argument of the quantitative-qualitative debate is that the underlying philosophies and methodologies appear to be so oppositional that these paradigms are completely incompatible, and that any attempt to reconcile the differences would destroy the philosophical foundations of each paradigm (Lincoln, Lynham et al. 2011). However, it has been argued that the different strengths and limitations of the quantitative and qualitative paradigms are complementary and using them together results in a richer understanding of the research conclusions than using one paradigm alone (Maxwell and Mittapalli 2010).

Further consideration needs to be given to synthesising of the methods. Creamer (2017) describes mixing as the linking or merging of qualitative and quantitative components of a mixed methods study which is not present if those strands do not come together. Teddlie and Tashakkori (2010) describe that a study which incorporates qualitative and quantitative elements, but those components do not link together as a quasi-mixed methods study. Therefore, central to a mixed methods study is the synthesizing of the qualitative and quantitative elements with at least one point of integration, or the point of interface (Schoonenboom and Johnson 2017). This is the point at which those qualitative and quantitative elements are linked. Teddlie and Tashakkori (2009) describe four points in the research process in which integration can take place: the stage of conceptualisation of the study; the data collection stage or methodological design; the data analysis stage and the inferential or findings stage. Schoonenboom and Johnson (2017) considered that this description needed further refinement, and based on the definition by Guest (2013) they define the point of integration as being any point in a study where two or more elements of the research methods are linked in some way. Thus, the study presented in this thesis can be described as truly mixed methods. This study was designed in three phases, each phase

dependent on informing the next phase and method. Phase I was designed as a national survey; a questionnaire was developed and the Royal College of Nursing Rheumatology Forum was engaged to distribute the questionnaire to its members in order to capture as wide a response as possible. This allowed a general exploration of how nurses are trained to give information about Methotrexate to patients in consultations. This phase then integrated with the next phase of the study, Phase II, the semi-structured interviews. The findings which resulted from Phase I contributed to the development of the interview schedule for Phase II. Having a broad understanding of how nurses are trained and how confident they are in their role, was integral to the interview schedule as it allowed the researcher to explore, in more depth, the experiences and perspectives of the training the nurses had and how they felt about it. It also added greater depth to the interview as the researcher was also able to explore how confident the nurses were and how they viewed their interactions with the patients. The final phase of the study, Phase III the video-recordings, added another dimension to the research. The first two phases contributed to the general and the nurses' personal perspectives of the phenomenon under study, but Phase III contributed to the actual perspective. The video-recordings allowed the researcher to visualise and score the phenomenon resulting in findings which informed and supported the first two phases of the study. Schoonenboom and Johnson (2017) consider that the merging of data sets and the connecting of the findings from one set of data collections to a second set of data collection constitutes points of integration. Thus, it can be argued the study presented in this thesis is a truly mixed methods study with points of integration as described above.

3.6 Phenomenology

A phenomenological methodology was applied in the design and analysis of Phase II of the project. The concept of phenomena as a philosophy began to take shape in the 18th and 19th centuries where things took place in the mind, rather than being observable realities (Smith 2008, Converse 2012). Immanuel Kant, who was a German philosopher in the later 18th Century (Smith 2011, Converse 2012), believed that a phenomenon was a manifestation in the human mind which was separate from reality and not perceived by human senses. Hegel et al (1977) considered that phenomenology was the way to study the journey from natural consciousness to real knowledge. Jasper (1994) proposes that the beliefs which underpin the

nature of phenomena are reality, subjectivity, and truth summarised in Table 3.7.

TABLE 3. 7 PHENOMENOLOGICAL PERSPECTIVES (JASPER 1994)

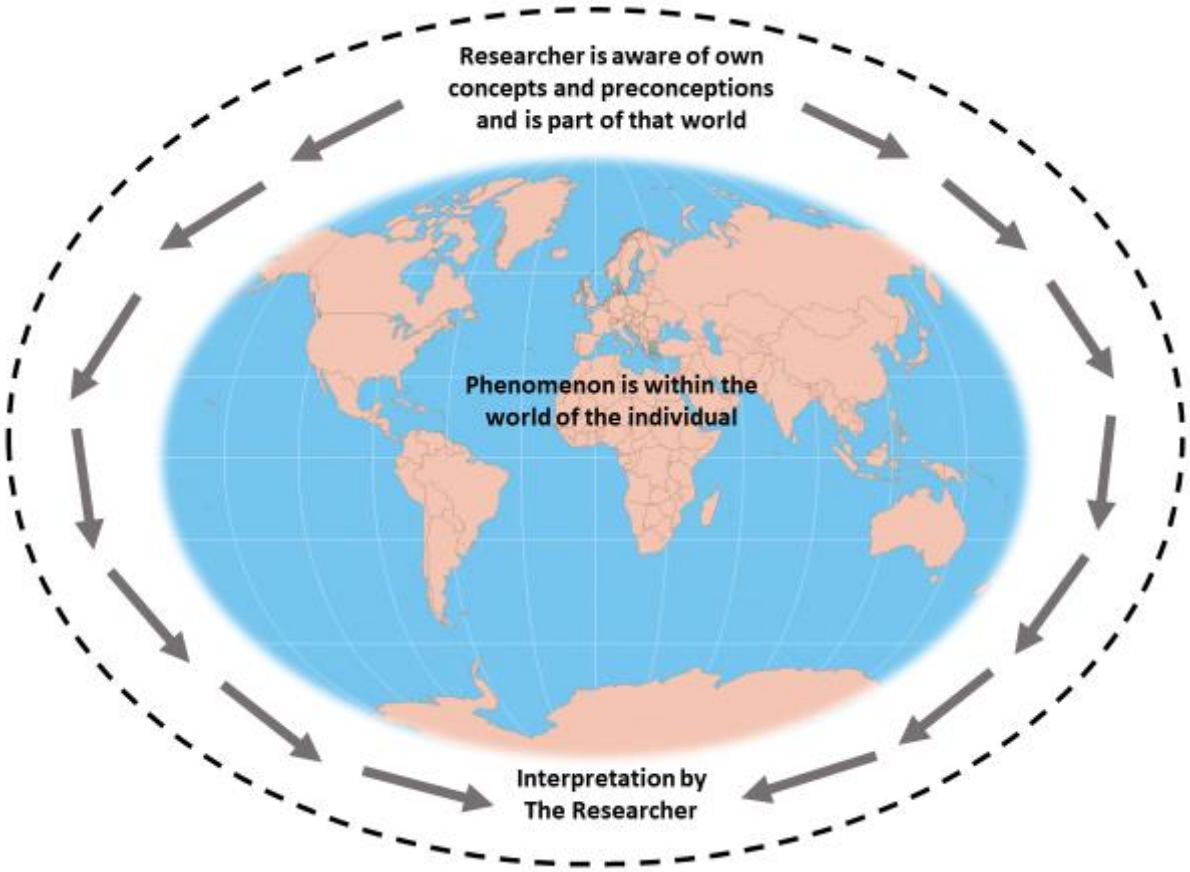
Feature	Belief
Phenomena	Objects and events as they appear with the assumption that there is a world, and that it is social in nature
Reality	Expected to be subjective and perspectival, reality is a matter of appearances
Subjectivity	As one resides in the world, it becomes real through contact with it, this knowledge then shapes experience
Truth	This is a combination of realities and these realities are read through forms of expression therefore giving the researcher a way into the subject's reality

Phenomenology seeks truth and logic through critical and intuitive thinking (Jones 2001) therefore it is a means of discovering human experience going beyond factual accounts seeking to give meaning to the experiences of individuals. Husserl, a German philosopher (1859-1938) (Converse 2012) considered that in order to reach real knowledge, the researcher must strip away their own pre-conceptions about a phenomenon, to revel the true essence of that phenomenon. This approach is viewed as a trademark of Husserlian phenomenology (Flood 2010) and Oiler (1982:181) wrote that the ability to bracket allowed the researcher to:

"…look(ing) at the experience with wide open eyes, with knowledge, facts, theories held at bay; concentrating on the experience is absolutely necessary. becoming absorbed in the phenomenon with being possessed by it, is equally important".

However, Heidegger, who studied under Husserl, took phenomenology into a different direction. He believed that the person and their experiences were an integral part of the world and therefore contributed to that knowledge. He developed the "Hermeneutic Circle" (Figure 3.6) in which the researcher must be aware of his own conceptions or his "fore-having; fore-sight and fore-conception" (Heidegger, Macquarrie et al. 1962).

FIGURE 3. 6 A PERSONAL CONCEPT OF THE HERMENEUTIC CIRCLE BASED ON (HEIDEGGER, MACQUARRIE ET AL. 1962)



Thus, the researcher's own feelings and judgements are part of the world and the phenomenon. Instead of adopting a reductionist approach to phenomenological research as argued by Husserl by "bracketing out' preconceived assumptions, Heidegger shifts the focus of the researcher from revealing the essence of the phenomenon to understanding the phenomenon in relation to the researcher (Converse 2012).

Heideggerian phenomenology contributes to nursing research as it revels the descriptions and meaning of experiences of the people who are the focus of study (Pratt 2012) and was therefore considered an appropriate methodology for this project. Phase II of the project aimed to understand the experiences of the nurses who were undertaking the Methotrexate education consultations and what that experience meant to them. This methodology is becoming increasingly relevant to nurse researchers; a fundamental element of nursing

practice is the embracing of holistic care, being a patient advocate and providing support both physical and psychological to patients, their families and carers and valuing all of the life experiences of these people (Moxham and Patterson 2017). Nurses generally have an instinctive desire to understand the patients they are caring for, and ultimately want to do their best for them (Berkowitz 2016). Therefore, the personal perspectives and lived experiences of the nurse researcher would be more aligned with the Heideggerian phenomenological standpoint to reach a deeper understanding of the experiences of the subjects under study.

The key elements of phenomenology are described by Proctor (1998) as a belief that the world is socially constructed and subjective and individuals give meaning to their own world view. Proctor believes that the purpose of phenomenological research is to deepen understanding of the perceptions and meanings which individuals hold, and that the researcher becomes part of the environment under exploration. Proctor also considers that in phenomenology the research is neither value free or objective and findings emerge from the field under study which results in understanding rather than generalisability.

3.7 Trustworthiness of Qualitative Research

There are no formulas for working out which qualitative research method to adopt and which approach to take when designing a research study, however a number of approaches have been developed to assess qualitative research work. Dixon-Woods et al (2004) acknowledge that qualitative research can make a significant contribution to healthcare services but they recognise that there has been a tendency to treat it as a unified field, which does not take into account the number of different methodological approaches which can be utilised.

The trustworthiness of qualitative results is often criticised as being open to manipulation by the will of the researcher, for example, how it can be demonstrated that themes and quotes extrapolated from the data are not reinforcing a pre-existing view. In contrast, the overall impression is that quantitative results are more objective as they are generally based on numbers and statistical analysis. Quantitative studies are, however, equally open to biased interpretation. For example, a researcher could be selective with the analyses reported, and

figures could be manipulated in such a way as to achieve the researchers overarching aims. In the pharmaceutical industry, the opportunity to bias study results has been minimised by the registration of these studies with pre-specified analyses and the availability of the raw data for scrutiny (Ioannidis, Greenland et al. 2014).

Various recommendations have been made about how to build "trustworthiness " into qualitative research and COREQ have published a checklist of 32 items for people reviewing papers for publication (Tong, Sainsbury et al. 2007). These 32 items were developed to promote clear and complete reporting of qualitative work. However, they only reviewed work around semi-structured interviews and focus groups as they considered that these were the two most common methods used for qualitative data collection. Whilst the 32 items they developed are useful, they are limited as they rely on face-to-face contact. However, this checklist was a useful guide for Phase II of the study presented in this thesis a completed checklist (see Appendix 6).

Houghton et al published a nursing perspective on rigour in qualitative research and describe strategies that could be applied to build trustworthiness into qualitative research (Houghton, Casey et al. 2013) including triangulation, comparing data from at least two sources for agreement, peer debriefing, the on-going discussion of the study with people unrelated to data collection which could be in the form of a presentation at a conference or discussion with a supervisor. Member checking is the process of checking with the participants that they agree with the findings of the study. Reflexivity is a process of self-reflection by the researcher concerning how their own beliefs, experiences and perspectives may have influenced the findings of the study. Thick description relates to ensuring that there enough of the raw data has been described to allow the reader to judge the conclusions and the transferability of the study findings. Hadi and Closs (2016) describe a similar list of features and suggest that a study should use at least two of these. Peer debriefing has been carried out throughout the study presented in this thesis. Regular discussion has been maintained with the researcher's supervisor and emerging findings have been presented at national conferences (Robinson, Ryan et al. 2015). Triangulation of data has also been applied to this study; the Phase III data resulting from the video-recordings was analysed using three methods, thematic analysis (see Chapter 5 section 5.16.1), Medical Interaction Process System

(see Chapter 6 section 6.4.4) and analysis using the Calgary Cambridge scoring (see Chapter 6 section 6.4.3). Further, the researcher described a reflexive account in order to maintain transparency and highlight any potential biases which may have been introduced to the study and findings (see Chapter 3 section 3.10). Hadi and Closs (2016) went on to analysed ten qualitative studies consisting of interviews or focus groups with thematic and framework analysis and found that the most commonly used strategy was thick description in nine of the studies and peer debriefing in five. To this list, Morse (2015) added "negative case analysis" reviewing outliers who have a non-typical standpoint. Detailed review of these can give a more robust view of the "norm"; clarifying research bias in other words, have the research participants been identified in an appropriate manner? External audits Morse suggests are only appropriate for "suspect" studies where the results are "too good to be true". Morse also discusses using standardised codes for analysis, which would be used in all similar studies. This would certainly make the results more reliable but at the price that insights that would have been available with interpretive coding would be lost. Morse recommends five strategies for establishing reliability in qualitative research (Table 3.8).

TABLE 3. 8 STRATEGIES FOR ESTABLISHING REALITY IN QUALITATIVE RESEARCH (MORSE 2015)

Strategy	Reliability	Comments and Cautions
Development of a coding system and inter-rater reliability	Only for semi-structured interview research	Coding system and code book are needed
Member checks	Does the researcher understand/interpret the participant correctly?	You need to understand the participant
Thick description	Provides opportunity for seeing replication/duplication	Interviews overlap, verifying the data set
Peer review debriefing	Could be an issue with team research	
External Audits	Do not impact on reliability and are rarely used	If done, it would be after the event, therefore too late

The five strategies recommended by Morse (2015) appear to relate to semi-structured interview research. However, it could be argued that these strategies could be applied to the

analysis of video recordings. Whilst Morse seems to say that the development of a coding system which contains inter-rated reliability checks should only be used with semi-structured interview, this approach would work well with video-recordings. Indeed, these five strategies align with the Medical Interaction Process System developed by Ford et al (2000) which was used to analyse the video recordings in Phase III of this thesis. Morse (2015) also recommends an external audit, which may be too late as the study may have ended. However, Cope (2014) would say that the maintenance of an audit trail throughout the research activity, is key to enhancing the credibility of qualitative research. This audit trail would comprise of the field notes and decisions made by the researcher, during the research journey, this information would add to the validity overall conclusions and could be reviewed by others to determine if they would arrive at the same deductions.

3.8 Insider Research

Insider research refers to conducting research in an organisation or culture in which the researcher belongs (Hewitt-Taylor 2002). Historically, insider research was undertaken in ethnographic studies in anthropology and sociology (Hellawell 2006). However, insider research is now being conducted across many disciplines including nursing (Toy-Cronin 2018). A key advantage of insider research has been described as having the "pre-understandings" that the researcher brings to the study and therefore have insights from the lived experienced (Brannick and Coghlan 2007, Costley, Elliott et al. 2010). It could be considered to lend more credibility to the research as it has been undertaken by a member of the community under inquiry (Costley, Elliott et al. 2010). However, insider research can also be seen as problematic in that the researcher may have a personal and emotional investment in the study and could find it difficult to detach their own experiences from those of the participants which may impact on the study findings (Alvesson 2003). The individual motivations of the researcher are generally unknown, a reflexive statement on the effects of the researcher's views and their connection to the research would acknowledge more transparency and strength to the results. Kitto et al (2008) recommend that throughout the study the researcher should maintain a reflexive perspective adding to the transparency of the work.

There are arguments that undertaking a process of reflexive awareness, can result in a richer research inquiry (Brannick and Coghlan 2007, Finefter-Rosenbluh 2017). Reflexivity is a process in which the researcher turns the inquiry to themselves, and takes responsibility for their own position within the research, being transparent about the effect they may have had on the data collection, participants and data interpretation (Berger 2015). With reference to this thesis Phase I, was a national survey and whilst it is possible that the researcher would have been known by some of nurse participants, the insider viewpoint of the researcher did contribute to the development of the survey questionnaire. Phases II and III of this study, did position the researcher as an insider, and thus a reflexive perspective was undertaken by the researcher and described in the following sections of this chapter. However, further discussion of the ethical considerations when conducting insider research will be discussed in the next section.

3.9 Ethical Considerations

It is beyond the scope of this thesis to present a full discussion of ethical considerations when undertaking research, therefore this discussion will centre on the ethical considerations of the study presented in this thesis. The twentieth century saw crimes committed against racial and ethnic groups and vulnerable populations in the name of research, as a direct result of this, a set of rules was developed to attempt to enforce good clinical practice when conducting research (McGraw, George et al. 2010). In the 1990s the regulatory authorities for Europe, Japan and the United States formed the International Conference on Harmonisation Good Clinical Practice and developed guidelines for research and compliance with these guidelines ensures that rights, safety and well-being of research participants are protected (Kaur and Choy 2014).

Informed consent is an essential part of the research process and should be given freely with full understanding of what is being asked of the participant. Consent often takes the form of a written and signed statement by the participant and the researcher, but in some cases it can be implied, through completion of a questionnaire for example (Connelly 2014). Thus, consent for Phase I of this study involved implied consent, as this was given through the completion of the questionnaire by the participant. A phenomenological methodology

seeks to investigate lived experiences, therefore consideration must be given by the researcher of the sensitivity of the data and how far the participant wants to self-disclose (Walker 2007). The next two phases of the study presented in this thesis encompassed a phenomenological perspective, therefore the researcher developed Participant Information Sheets and Consent Forms, specific to that phase of the study to ensure that the participants were aware of the aims and objectives of the study and were therefore fully informed that their experiences and perspectives would be discussed. A further consideration of informed consent is that participants must be aware that they can withdraw from the study at any time (Polit and Beck 2014) therefore this was written into the Participant Information Sheets. A further ethical consideration considered for this study was that the researcher may have revealed behaviour by the nurses which could put patients at risk. This was discussed in the Participant Information Sheets, and participants were made aware that should the interviewer have concerns they would be discussed with the participant immediately and would agree further action if necessary.

Munhall (2012) argues that one of the most critical and ethical obligations of the researcher is to faithfully describe the experiences of the participants being researched. Thus self-reflection and external review by the researcher to identify beliefs, assumptions and preconceptions about the research topic is an important strategy in order to add authenticity to the resultant findings (Burns and Grove 2010).

3.10 Reflexive Perspective of the Researcher

Several authors believe in the value of revealing the reflexive position of the researcher undertaking the data collection and analysis in order to induce transparency and quality control (Payne and Payne 2004, Neale 2008). Researchers need to be cognisant of their contributions to the research process (Palaganas, Sanchez et al. 2017). Therefore, the following is a reflexive account of this researcher.

I am a Specialist Nurse who has had no specific training for my role, and I have “learned on the job” gaining knowledge whenever it appeared. My interests lie within the educational development of nurses once they have achieved their registration. The field of Rheumatology

has advanced dramatically over the last 25 years, with new and effective, but toxic drugs now being used to treat patients. (Kaneko 2013, Choy, Freemantle et al. 2019, Genovese, Kalunian et al. 2019) This resulted in the closure of Rheumatology wards in the UK, with most patients now being treated on an outpatient basis. As a direct result of this, nurses now find themselves running outpatient clinics with their own patient lists, making treatment decisions and having a direct impact on patient care.

As discussed, in Chapter 2 (section 2.4), nurses working in the field of Rheumatology, do not receive any specific training in order to become specialists within this area of Medicine (Royal College of Nursing 2009). There is a strong reliance on the nurses themselves to seek out knowledge and apply it within their roles. This often leaves those nurses, under confident and without any depth of understanding of Rheumatological conditions and their treatment. The sources of information that Rheumatology Specialist nurses often use, are designed primarily to be used by patients. It was this situation that prompted me to explore what was happening throughout the country, to understand if there were better learning opportunities in other Trusts and services, to determine if there were "gold standard" Rheumatology training courses that nurses throughout the country could attend. I understood that this could be a mammoth task, therefore I refined my exploration and decided to take one aspect of patient care to look at in more depth. Methotrexate is a widely used drug in the treatment of Rheumatology conditions, particularly Rheumatoid Arthritis. It is a toxic drug and requires the patient to understand why they are taking it, how to take it and to recognise possible side effects and take appropriate action. It is one of the prime responsibilities of the Rheumatology nurse, to ensure that the patient has this information, understands it and takes the drug appropriately. This was a task I had to perform when I became a Rheumatology Specialist nurse over 15 years ago. I was given very little opportunity to gain any in-depth knowledge of Methotrexate and I had no training at all in conducting consultations with patients, which was not a satisfactory position to be in. I therefore have a real understanding of undertaking this important function, without good training, and the feeling of under-confidence that emerged. Further, because I understand the role, I was able to establish a common relationship with the nurses, which helped me to recruit them to be interviewed and video-recorded.

Phase I of this study was to design the national nurse survey. I reflected on my own experiences to develop the questionnaire used in the survey, how I gained knowledge about

Methotrexate, conducting consultations and drawing on situations I have commonly confronted. The questionnaire was validated by Rheumatology nurse specialists at a regional meeting. This ensured that the questions were clear, unambiguous, would commonly be confronted by other nurses and reduced any bias that I may have unconsciously contributed. An interview schedule was designed for the next phase of the study, in order to ensure that the same questions were put to the interviewees. This interview schedule was also validated by experienced colleagues to ensure that the questions were pertinent to the research question. Whilst I may have consciously or unconsciously responded at times to the interviewee with head nods or umms and ahhs, this was consistent throughout each interview, but it may have added limited bias to the interviews.

Throughout conducting this research project, I maintained awareness that my experience may not have been everyone's. I did understand however, those aspects of conducting a consultation with a patient when talking about Methotrexate, which can cause some pressure for the nurse. For example, I understood that time limits create a lot of pressure on the nurse, to focus on the job in hand ie giving the patient the information about Methotrexate, which left little else for the nurse or patient to discuss. I also understood the reticence the nurses had around being video-recorded. Unlike other healthcare professionals such as Doctors and General Practitioners, who use video-recording to analyse their practice regularly, nurse do not, therefore they are less confident with this approach. However, as I personally knew all of the nurses involved, they were more comfortable agreeing to be video-recorded. They were all confident that I would protect their identities and destroy the recordings when the analyses were complete. They were also aware, that if I identified anything during the analysis of the recordings, that required their attention, I would approach them first and discuss and plans of action that may have been required. However, this was not required. In order to maintain a comfortable environment for the nurse and the patient, the video was set up and left in the room, whilst I waited outside. The objective of this was to create less pressure on the nurse and therefore reduce the awareness that she was being video-recorded. I found that after the first few minutes, the nurse and patient reported that they forgot the video was in the room. However, having an awareness of the pressure and feelings of the nurses helped me to understand the nurses' behaviour in a way that other researchers may not relate to.

Whilst I did, at all times, try to be aware of my own position, experience and feelings, it is possible that some bias did creep into the resultant analysis, however, this would have been consistent throughout the data gathering and analysis process and therefore, in my opinion, would have limited impact on the conclusions.

3.11 Chapter Conclusion

The overarching aims of this study required three phases in order to explore these goals. This study was designed with critical realism as the underpinning philosophy as it was felt to be the most appropriate for the study. As discussed in this chapter, critical realism explores three domains, the real, the actual and the empirical. When applied to this study, the real domain reflects Phase I, the national questionnaire which seeks to determine how nurses are trained and to test their knowledge of Methotrexate. The second domain, the actual, is represented by Phase III, the video-recordings to identify the actual processes which take place when nurses give information to patients about Methotrexate during their consultations and the third domain the empirical, is represented by Phase II, the semi-structured interviews, which seek to explore the feelings and perceptions of nurses when they conduct this role. Further, the methodological approaches to the analysis of the semi-structured interviews and video recording transcripts adopted a phenomenological position. This seeks to understand the experiences and feelings of individuals within the world scene. The researcher adopts a reflexive position to understand their own perspectives and experiences and how this may affect the research. Further, as an insider researcher, this reflexive position of the researcher for the study presented in this thesis has been described above.

Chapter 4: Phase I – A national survey of nurse training: confidence and competence in educating patients commencing Methotrexate therapy

4.1 Introduction

This chapter begins by expanding on the previous literature review with a particular emphasis on the role of the Rheumatology Specialist nurse. This role evolved during the 1980s, with nurses taking on tasks such as assessing joint for tenderness and swelling, mobility and function (Bird 1981). The introduction of new drug therapies for the treatment of Rheumatoid Arthritis led to increasing specialisation for Rheumatology Specialist nurses and they began to take on the role of managing patients on these revolutionary and life changing drugs (Hill 1992). These roles further developed and nurses took on prescribing of drugs and teaching medical students (Goh, Samanta et al. 2006), by 2009 nurses were also carrying out cognitive behavioural therapy and biomechanical assessments (Royal College of Nursing 2009). It also showed that whilst there is general recognition amongst nurses of the importance of shared decision-making and the impact of this on patient education (Hoving, Visser et al. 2010, Flanders 2018, Sassen 2018), it was not clear how the nurses gained their knowledge regarding how to implement this in a consultation with patients. There appears to be a general paucity of research that has been undertaken to investigate Rheumatology Specialist nurses' knowledge with regard to their preparedness for the specialist roles, which have developed over the last 40 years. The literature clearly reveals that effective patient self-management led to more effective care and patient empowerment (Bain, Sangrar et al. 2016, Bearne, Manning et al. 2017, Garattini and Padula 2018) but the learning pathways available for nurses to gain the skills to guide, teach and support patients to embrace self-management is, again, not clear in the literature. A survey conducted by Mathijssen et al (2020) explored the knowledge attitude and experiences of shared decision-making of doctors and nurses in Rheumatology. Their findings showed that 100% of nurses recognise the importance of putting the patient at the centre of care through shared decision-making, however they concluded that they were experiencing problems putting

this into practice. What was not clear was how the nurses were trained to conduct consultations and give information to patients. Reviews of literature regarding the knowledge that Rheumatology Specialist nurses have about Methotrexate, showed that most studies explored patient knowledge rather than nurse knowledge. The studies around patient knowledge of Methotrexate showed that there is a general lack of understanding of the side effects of the drug and how to report these side effects (Sowden, Hassan et al. 2012, Fayet, Savel et al. 2016). Whilst it is beyond the scope of this thesis to determine exactly why many patients appear not to have a clear understanding of the possible harmful side effects of Methotrexate, it could be speculated that one of the contributory factors could be how the information has been given to the patients. Thus, this phase of the study aims to contribute to the extant body of work by exploring though a national questionnaire, how nurses gain knowledge about how to give information about Methotrexate, how confident they are in this role and how long it takes to become confident. The questionnaire will also explore nurse knowledge of Methotrexate through some scenarios which would commonly be encountered by nurses.

Questionnaire surveys have been utilised by researchers to determine knowledge of drugs; in 2001 Latter et al (2001) recognised that nurses had a potentially important contribution towards the education of patients about medications and carried out a national survey of student nurses on their knowledge of drugs and their attitudes towards patient education. The results of their study demonstrated that there was little opportunity to apply their knowledge and to gain experience and the attitude seemed to be that they would learn on the job. Courtenay and Carey (2008) carried out a national questionnaire survey of diabetes nurses who were prescribing medication. The aim of the survey was to determine how educationally prepared nurses were for prescribing because:

"*there was very little or no evidence on the prescription of medicines by nurses for people with diabetes or whether nurses feel prepared for this role*" (Courtenay and Carey 2008:404).

The authors recognised that nurses had varying levels of expertise and were working in a variety of clinical roles. All nurses surveyed had undertaken a medication prescribing course. Interestingly, of 439 questionnaires analysed, 45% of respondents did not have formal qualification in Diabetes; their education was through study days and in-house

training by shadowing a nurse or doctor in their department, which shows a similarity to Rheumatology Nurse training. They found that approximately 50% of the questionnaire participants felt that their needs were not met by the prescribing course they had undertaken. A further survey in Diabetes was conducted by Hollis et al (2014) to explore whether practice nurses had enough knowledge to provide self-management education to diabetic patients. Like Rheumatoid Arthritis, Diabetes is a chronic disease, which requires life-long medication and management. They designed a questionnaire to collect demographic data, and 14 multi-choice questions addressing diabetes pathophysiology, blood glucose levels and monitoring, dietary issues and medication management. They found that there was a lack of knowledge in some areas of dietary advice and that medication knowledge was poor, despite pharmacotherapeutics being a mainstay of diabetes management. They concluded that those nurses that had undertaken a postgraduate course had scored better, but there was a general lack of education preparedness for this role. However, they did not specify what kind of training the nurses had undertaken or how many of their study population had completed courses or had just learned on the job. Surveys have also been carried out around perceptions of the Rheumatology nurse's role (Goh, Samanta et al. 2006, Royal College of Nursing 2009). Phase I of the study is the first national survey examining the education and knowledge of nurses in Rheumatology who educate patients about Methotrexate. The survey was necessary because nurses had expressed variable confidence in their educational role (Royal College of Nursing 2009) and the use of Methotrexate had increased dramatically over the last twenty years. Discussions with other Rheumatology Specialist nurses at national conferences, workshops and meetings, had highlighted that training for nurses performing this role is necessary, that it is often organized locally and varies in content, but there is a dearth of published material to support this view.

An aim of the questionnaire survey was to determine the basic knowledge that Rheumatology Specialist nurses have about Methotrexate. Much of the information that the patient needs to effectively and safely take drugs like Methotrexate is contained in patient information leaflets such as that produced by Arthritis Research UK now Versus Arthritis (2019). To educate a patient effectively, a nurse will need to understand this information, have the skills to enable the patient to understand it, and have the knowledge

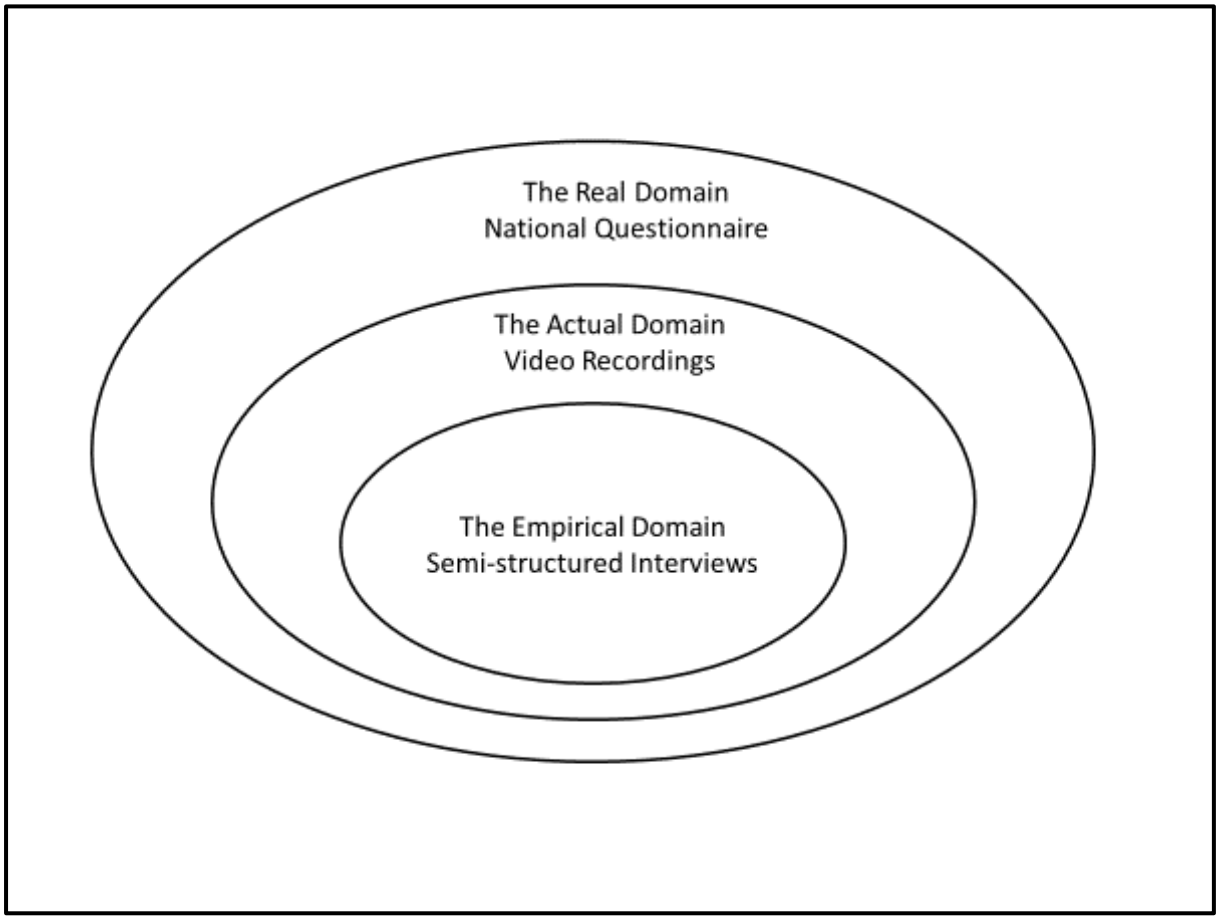
and understanding to answer the patient's questions and recognise concerns that they may not verbalise as well as provide the opportunity to address any lay beliefs about medications. Therefore, the questionnaire survey explored how far the nurse used this information leaflet when giving information, and determined if the nurses utilised other information sources. Effective patient education is important; Jones et al (2011) recognise that effective patient education enhances knowledge and understanding of disease which could affect their confidence in shared decision-making and self-management. They also reported that the failure to provide information for patients about their condition is one of the most frequent sources of complaint. They also go on to state that whilst healthcare professionals are well informed, they have rarely been trained to provide patient education and therefore they designed a course in Oncology to try to address this gap. In the field of coronary care, Svavarsdottir et al (2016) report a similar gap in the skills of healthcare professionals and they conducted a study to investigate healthcare professionals' views on the knowledge and skills required to give effective patient education. They interviewed 19 healthcare professionals including nurses who worked in cardiology, they all agreed that advanced knowledge was important, and some informants implied that educating and counselling relied on those skills that were picked up through experience. Svavarsdottir et al concluded that effective training is needed for healthcare professionals to acquire the competencies which would enable their patients to better manage their disease.

To reiterate, this phase of the study aims to contribute to the body of work undertaken on nurse training and identify how Rheumatology Specialist nurses are currently trained to carry out their role in order to give information on Methotrexate to patients and what information sources they use to support their role. Furthermore, it aims to reveal how confident nurses are in actually undertaking this responsibility and how long it takes for them to become confident. Additionally, an exploration of the level of knowledge nurses currently have about Methotrexate was undertaken to identify the level of competency they have when counselling patients about Methotrexate. This survey will inform the later phases of the study, particularly the interview schedule.

As outlined in Chapter 3 (section 3.4), the philosophical underpinning of this study is critical realism. Within this philosophical framework, phase I of the study represents the

investigation of the real domain (figure 4.1). The next section of this chapter reports the methods used to design the questionnaire and collect data.

FIGURE 4. 1 INVESTIGATION OF THE REAL DOMAIN- QUESTIONNAIRE



4.2 Aims and Objectives of Phase I

4.2.1 Aims

The aims of the national survey were to explore the training that Rheumatology Specialist nurses had received for educating patients about Methotrexate. Further, to identify their confidence in conducting this role and to evaluate their knowledge around clinical situations relevant to Methotrexate use. The aim of this is to reveal if any further training is required.

4.2.2 Objectives

1. To obtain data regarding training, qualifications and experience through a national questionnaire.
2. To gauge nurses' views regarding confidence and the time it takes to become confident in conducting this role.
3. To assess levels of knowledge Rheumatology Specialist nurses, have about Methotrexate.

4.3 Methods

4.3.1 Study Design

In order to capture the responses from Rheumatology Specialist nurses from a wide geographical area, a questionnaire was developed. The questionnaire was designed to collect quantitative and qualitative data, using closed and open questions. This questionnaire was informed by a review of the literature, as described in Chapter 2 carried out for this thesis. The use of questionnaires in healthcare is increasing (Rattray and Jones 2007, Gupta, Nayak et al. 2015) in order to capture data on areas such as beliefs, training and knowledge. The rationale for adopting a questionnaire design for this phase of the study was to ensure it was generalisable across practice in England and collect as much data as possible over the widest geographical area using an on-line platform. This phase represented the real domain of critical realism and aimed to explore how nurses were trained and test their knowledge of Methotrexate on a national level. The domains of the questionnaire focussed on:

1. Training
2. Confidence
3. Time to become Confident
4. Knowledge

Demographic data were not collected as it was not considered that it would add to the exploration of the aims of the study, however the year that the nurse had obtained their

registration was collected, as the length of time the nurse had been qualified may relate to confidence. The content of the domains was more difficult to determine as relatively few questionnaires have been carried out on Rheumatology nurse training. However, the RCN questionnaire (2009) was a starting point as it explored the performance and activities of Rheumatology Specialist nurses. It addressed questions around years working in Rheumatology and qualifications since nurses' graduation and a section on competencies and confidence. Whilst the RCN questionnaire was more detailed, it generated guidance in the design of this study questionnaire. The domain on knowledge was developed from the extant literature on the side effects of Methotrexate, discussed in Chapter 2 (section 2.3.3.1) of this thesis. The side effects of Methotrexate can be diverse and occasionally life threatening (Gaies, Jebabli et al. 2012) therefore nurses require a competent knowledge of these. Consequently, the survey questions on knowledge were based on common problems which have been identified in the literature (Gilani, Khan et al. 2012, Ledingham, Gullick et al. 2017).

4.3.2 Questionnaire Design

A survey is a complex communication process between the researcher and the participants where the results of the interaction lead to shared understanding and meaning (Lietz 2010). There needs to be agreement about what to ask within the framework of the research questions, then the questions are developed which encode the request for information, finally participants decode this stimulus and provide an answer. The researchers then decode the answer from the participant and derive meaning from it (Hunt, Sparkman Jr et al. 1982). Another perspective starts with a cognitive approach to surveys, where responding to surveys involves a number of phases of reasoning and information processing (Aday and Cornelius 2006). It also relies on a truthful judgement from the participant and their motivation, and the respondent's answer is co-ordinated with the questionnaire categories (Holbrook, Cho et al. 2006, Lietz 2010). The use of surveys in healthcare research is on the increase (Piko 2006, Rattray and Jones 2007, Delobelle, Rawlinson et al. 2011, Gupta, Nayak et al. 2015) and nurse researchers often use questionnaires to measure domains such as knowledge, attitudes, emotion, cognition intention and behaviour. This approach allows the researcher to capture the self-reported interpretations of the participant and is often used to measure patient

observations of health care (Rattray and Jones 2007).

There are a number of considerations which should be considered when developing questionnaire items. For example Holbrook et al (2006) identified that longer questions could increase the demands on memory for a participant affecting their response, however, a longer question may be the result of the researcher taking time to clearly describe the intent of the question and this could result in less cognitive demand. It is also suggested that responders interpret a question as it is read, and may not reach the end of the question before responding. Questions which require higher reading levels could result in greater understanding of difficulties as they require more cognitive resources. However, it could be said that these questions may be explained more fully allowing the participant to comprehend the question better. Abstract questions are those which are not related to a specific context, they may be ambiguous or vague which could affect the respondent's ability to comprehend. There are also a variety of formats which can be used for questionnaire items, for example open ended questions, closed questions, yes/no, Likert scales. Confusion could arise where the response is not clear, for example "sometimes" "occasionally" "somewhat" participants may interpret those responses differently. Similarly questions with a numeric response could present a challenge for the responder appearing confusing or being misinterpreted. Qualified judgement, questions where the time frame is qualified for example; "in the past five years have you…" or "how much pain have you had in the past week…" can pose problems for the responder as they have to both keep in mind the question and yet qualify their judgement when answering.

There are a number of advantages to using questionnaire surveys as a research method (Gillham 2008). A lot of information can be captured relatively quickly, and the participants can take as much time as they need to complete their responses. The analyses of closed questions with a definitive response are straightforward and participants can remain anonymous if this is built into the survey. All participants answer the same questions and they can provide data to test a hypothesis.

Gillham (2008) also describes some disadvantages of questionnaires as some participants may not complete the whole questionnaire. Motivating potential participants to complete the questionnaire may be problematic and could result in a low response rate. Questions could be

misinterpreted and cannot be corrected therefore the wording of questions can have a major impact on the answers given. There could also be issues with language, literacy and cultural influences. Further, the spoken word enables people to give richer and deeper responses to questions rather than the written word. It can also be difficult to check the honesty of responses and thus could reflect on the accuracy of the results.

It is therefore important to consider the context of the questions in survey design, and ensure that the wording and length of the questions is appropriate for the target audience in order to ensure that the resulting data is as meaningful as possible (Lietz 2010). Because of these potential limitations in terms of data reliability, pre-survey testing is essential in order to iron out any problems before the questionnaire goes live. It allows the researcher to re-visit and refine the questions to ensure, as far as possible, that the resulting questionnaire results are as reliable as possible and limit the possible responder misconceptions (Gillham 2008). A pre-survey was carried out for the study presented in this thesis in order to test the validity of the questionnaire and make any necessary changes and is described in more detail in this Chapter. Whilst the study questionnaire was developed by the researcher it was further commented on by two Rheumatologists and a Consultant Rheumatology nurse. Their experience in the field of Rheumatology was an important contribution to the first draft of the questionnaire. The questions were developed by the researcher and were based on situations which are commonly confronted by nurses who manage patients on Methotrexate. The questions also described situations which illustrated the common side effects and contraindications to Methotrexate. None of the questions had been used in other surveys; they were unique to this study. The questionnaire consisted of 26 questions which were divided into:

1. Background information about the participants (how many patients per week they talk to about Methotrexate, number of years they had been doing this role, number of years in Rheumatology, year of qualification).
2. Training to carry out the role of giving information to patients about Methotrexate (what training took place, was it helpful, would more training have been useful and if so what kind of training, confidence to carry out the role, how long this took, what written information the nurses used and the usefulness of the information).
3. Assessment of knowledge.

An open question was designed to captured data on a description of any prior training that had been undertaken by the Rheumatology Specialist nurse. This allowed the participant to describe their perception of how they had been trained and their experience of this could then be related. Confidence was evaluated using an eleven-point Likert scale, with zero being no confidence and ten being extremely confident. An 11-point Likert scale was adopted as it is easily comprehensible from zero to ten and the increased number of points make it closer to reality (Wu and Leung 2017). Knowledge was assessed using a closed format in the form of 12 scenarios based on clinical situations with a range of possible responses but only one correct answer. These two closed-question techniques allowed the responses to be captured numerically and therefore datasets could be compared.

4.3.3 Questionnaire Validity – Pilot Study

The questionnaire was piloted with a group of ten nurses at a regional Rheumatology meeting in order to check for face validity (Gillham 2008). The questionnaire was generally well received and the nurses felt that it was easy to complete. The modifications were confined to the clinical questions section where one ambiguous case was removed and two new cases added. The clinical cases focussed on scenarios relating to out-of-range blood tests, antibiotics which are not compatible with Methotrexate, when to stop Methotrexate before pregnancy, and what to do in a patient with shingles. These are common scenarios, which would be encountered by the Rheumatology Specialist nurse. The nurses all agreed that these were common and appropriate questions, however, the wording of some of the questions on the questionnaire were modified in response to their comments, thus ensuring that the focus of the questionnaire remained valid and understandable. The final questionnaire (see Appendix 7) was uploaded onto the Survey Monkey site, this web-based survey tool was chosen as it could capture a geographically wide sample of the target population and yield the highest number of responses possible (Chang and Vowles 2013).

4.4 Electronic Platform – Survey Monkey

Consideration of how the questionnaire survey was to be administered required some

attention. It is relatively easy to mail out or hand out questionnaires, but it is quite another thing to have them returned. A postal questionnaire study was undertaken by Jenkinson et al (2002), 3592 questionnaires were posted out to patients' home addresses, after two reminders were sent out, 2249 (65%) of questionnaires were finally returned. It could be said that this was not only costly, but time consuming not to mention that the patients had to get to a post box to return the questionnaires. Other researchers have opted to use an electronic tablet to capture responses to questionnaires (Parker, Manan et al. 2012) as they recognise that postal surveys can result in poor response rates. However, the barrier to this method is that the researcher has to be on site, capture each participant individually and there is a limit to geographical extent. Online survey tools are becoming a much more common platform to conduct healthcare research (Strickland 2012, Gill, Leslie et al. 2013, Merolli, Sanchez et al. 2014). There are many advantages to using online surveys as they are cost effective, quick to send, can easily reach the target population over a wide geographical area, participants can remain anonymous, reminders can be sent at no cost and results are collected in electronic format which makes it easier to build into databases and analyse the data. There are however some disadvantages, such as they require an email address for potential participants, they are difficult to police, in that questionnaires could be completed by participants who are not in the target population. It is easy for potential participants to ignore, miss or delete emails and without direct contact it could be difficult to motivate potential participants to complete the survey. The public and health professionals engage much more with the internet to discuss and investigate healthcare (Hamm, Chisholm et al. 2013, Moorhead, Hazlett et al. 2013, Denecke, Bamidis et al. 2015). One of the most common internet platforms is Survey Monkey. It is commonly used for market research but it can be used in a number of different domains including healthcare (Waclawski 2012). It is an online survey system with many design options and can be administered in different ways, such as by email or social media. Data collected can be downloaded, responses can be shared and reports can be created. It has many features which allow the researcher to send out and capture data effectively and ready to analyse.

4.5 Participants and Sampling

There are no national databases of Rheumatology Specialist nurses, therefore a web link to the survey was distributed through the online Royal College of Nursing (RCN) Rheumatology

Nurse Forum and the RCN newsletter. It was also sent to potential participants and colleagues within the UK known to the researcher in order to access as many Rheumatology Specialist nurses as possible. Participants were asked to forward the link to colleagues with a similar role. The survey was also distributed at a national meeting of the British Healthcare Professionals in Rheumatology (BHPR). There was no limit on how long the nurses had been working in Rheumatology.

4.6 Data Collection

4.6.1 Ethical Approval

Ethical Approval for phases I and II, was obtained from the NRES Committee North East – Sunderland in 2013 REC Reference 13/NE/0092 (Appendix 8). Approval was also given by Northumbria Healthcare Foundation Trust on 09/07/2013 to act as study Sponsor (Appendix 9). In accordance with Good Clinical Practice Principle (European Medicines Agency 2016), participant consent was implied through their voluntary action of completing the on-line questionnaire.

4.7 Data Analysis

The survey data were uploaded onto an Excel database and percentages for each response were calculated. Pearson's correlations were calculated to establish any correlations between confidence, knowledge, amount of training, time in education role and time to become confident. The alpha level was set at 0.05 for all statistical tests. Knowledge questions which had a correct or incorrect response were score by giving each correct answer one and zero if the response was incorrect. Qualitative data which was obtained through the open ended questions were analysed using content thematic analysis described by Green and Thorogood (2018) as firstly developing conceptual definitions, secondly, developing typologies and classifications, thirdly to explore associations between attitudes, behaviours and experiences, leading to the development of explanations of phenomena. Thematic analysis is discussed further in Chapter 5 (section 5.16.1).

All n=values are given in brackets are the number of respondents answering the questions, as this was not constant throughout the survey.

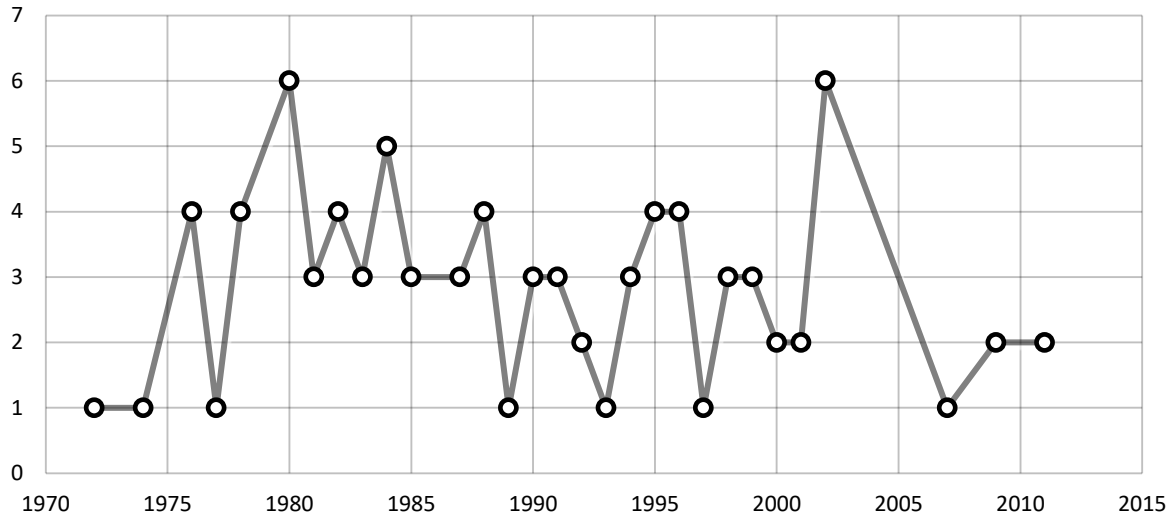
4.8 Results

104 nurses began the questionnaire, but seven (leaving n=97) were excluded as they answered no to “do you advise/educate patients with respect to starting Methotrexate treatment?” A further seven nurses (leaving n=90) dropped out of the survey in responses to “do you describe yourself as a Rheumatology Nurse Specialist?” Three nurses (leaving n=87) dropped out when asked “did you have any training before you took on this role?”, and two more respondents dropped out (leaving n= 85) when asked “how confident are you?” At the beginning of the knowledge questions one nurse (leaving n=84) dropped out before question 19, one respondent (leaving n=83) dropped out at question 23, five nurses (leaving n=79) dropped out at question 27 and finally one nurse dropped out at question 28, resulting in 74% (n=77) of the sample completing the survey. All responses were included in the results; therefore, all values and percentages represented the total of the valid sample responses for that question. Results are given as a percentage of respondents to each given question as well as number responding.

4.8.1 Background Information

68% (n=61) of respondents had qualified in the 1980s and 1990s, but they ranged from 1972 to 2011 (n=90) (Figure 4.2).

FIGURE 4. 2 CHART SHOWING YEAR OF QUALIFICATION OF RESPONDENTS



75% (n=68) of the valid sample (n=90) described themselves as Rheumatology Specialist nurses. Whilst 25% (n=22) of respondents described themselves as nurses who were involved in the blood safety monitoring of Rheumatology patients, they did have a role in giving information about Methotrexate, but did not have any other role in the patient's care. 63.9% (n=62) of valid respondents (n=97) had been giving information to patients initiating Methotrexate treatment for more than five years, 16.5% (n=16) of valid respondent had been doing this role for 1 – 5 years, 4.1% (n=4) had 6 – 12 months experience and 15.5% (n=15) of respondents had been giving information to patients for less than six months.

Most nurses give Methotrexate information to 1 to 4 patients per week (Table 4.1).

TABLE 4. 1 NUMBER OF PATIENTS PER WEEK THAT NURSES GIVE METHOTREXATE INFORMATION

Number of Patients Seen per Week	Responses (n=81)
1 - 4	52 (64.2%)
5 - 9	19 (23.5%)
10 - 15	6 (7.4%)
>15	4 (4.9%)

4.8.2 Training

Respondents were asked to rank their training on a scale from no training; some training or a lot of training (Table 4.2).

TABLE 4. 2 AMOUNT OF TRAINING NURSES HAD

Training	Responses (n=87)
No Training	12 (14%)
Some Training	61 (70%)
A Lot of Training	14 (16%)

Aimed at those nurses who had received training, respondents were asked if it was helpful on a scale of no help; some help; moderately helpful or very helpful, 50% (n=38) considered that it was very helpful, whilst 22.4% (n=17) found it moderately helpful and 26.3% (n=20) found it of some help (Table 4.3). The nurses were asked if they would have liked more training and 61% (n=53) of valid respondents expressed that they would.

TABLE 4. 3 HELPFULNESS OF THE TRAINING

Answer Options	Responses (n=76)
Very Helpful	38 (50%)
Moderately Helpful	17 (22.4%)
Some Help	20 (26.3%)
No Help	1 (1.3%)

In a four item-ranking question asking “what training do you think nurses need to educate patients about Methotrexate” (Table 4.4), of the 85 valid responders who completed this question 88% (n=75) of respondents considered that knowledge of Methotrexate was needed “a lot”.

TABLE 4. 4 WHAT TRAINING DO NURSES NEED

Answer Options	None	A Little	Some	A Lot	n=
Communication skills	1	4	18	62	85
Consultation skills	1	5	32	47	85
Knowledge	1	1	8	75	85
Experience	0	5	40	37	82

Some respondents also commented that they would like training on needle safety and disposal of cytotoxic materials. Also, further information on Rheumatological conditions and confidence in the drug itself underpinned by research evidence was added by some respondents. Seventy-three respondents described the training they had received, which included observing other nurses (n=23 31.5%), self-directed learning (n=18 25%) and observing Rheumatology clinics (n=10 15%). The results on training are summarised in Table 4.5.

TABLE 4. 5 REPORTED METHOD OF TRAINING RESPONDENTS HAD PRIOR TO COMMENCING THEIR DRUG COUNSELLING ROLE

Main Training Method	Number of respondents (n= 73)
Observing – other nurses and self-directed	49 (67%)
Observing – Rheumatologists Clinics	8 (11%)
In-house chemotherapy course	7 (9.5%)
In-house competencies	4 (5.5%)
Rheumatology Course	4 (5.5%)
Prescribing Course	1 (1.4%)

4.8.3 Confidence

The majority of the valid respondents (60%, n=51) for this question described themselves as ‘very confident’ in this role, with 24% (n=20) of respondents reporting being ‘confident’ and

12% (n=10) of respondents being 'somewhat confident'. 5% (n=4) of nurses were not confident at all (Table 4.6).

TABLE 4. 6 CONFIDENCE OF RESPONDENTS IN THEIR ROLE

Confidence Level	Number of Respondents (n = 85)
Very Confident	51 (60%)
Confident	20 (23.5%)
Somewhat Confident	10 (11.8%)
Not at all Confident	4 (4.7%)

The perceived time it took to become confident in the role was variable with 13% (n=11) confident in 0-2 months, 45% (n=38) in 3-6 months 20% (n=17) by a year, (a cumulative total of 78% (n=66) of the respondents) and for 21% (n=18) of respondents it took over a year. When nurses were asked if the way they gave information had changed from when they first started carrying out this role 42% said that it had "changed a lot" (table 4.7).

TABLE 4. 7 RESPONSE TO HAS THE WAY NURSES GIVE INFORMATION TO PATIENTS CHANGED?

Answer Options	Number of Respondents (n=85)
A lot	36 (42.4%)
In some ways	41 (48.2%)
Not at all	8 (9.4%)

Participants were also asked to comment on the changes that had occurred (see Appendix 10). Many comments related to gaining experience, enhancing knowledge and learning from patient's experiences which changed the way they gave information to patients. Some comments centred around patient empowerment and giving information in short bursts,

repeating messages and no longer using prompts. However, the use of checklists and proformas were also stated.

4.8.4 Written Information

Whilst most nurses reported that they gained confidence with time, most were using a variety of written patient information to support them in the process of giving information to patients about Methotrexate. Different sources of information were often used together. The Arthritis Research UK information sheet was used by 87% (n=74) and judged to be very helpful, but in-house information leaflets and information produced by the National Rheumatoid Arthritis society (NRAS) was preferred by some respondents (Table 4.8).

TABLE 4. 8 WRITTEN INFORMATION USED BY NURSES

Answer Options	Responses (n=85)
In-house Information leaflets	41 (48.2%)
Arthritis Research UK Methotrexate leaflet	74 (87.1%)
NRAS Methotrexate leaflet	22 (25.9%)

Twenty-three respondents reported that they had used other information including the National Patient Safety Agency booklet, Royal College of Nursing booklet, checklists and diagrams. The participants were also asked how useful this information was the results of which are presented in Table 4.9.

TABLE 4. 9 USEFULNESS OF THE WRITTEN INFORMATION

Answer Options	Responses (n=85)
Not useful	0 (0%)
A little useful	5 (5.9%)
Quite useful	21 (24.7%)
Very useful	59 (69.4%)

4.8.5 Knowledge

Knowledge was investigated using 12 possible real-life scenarios, the results of which are presented in the Table 4.10 to 4.21 below.

TABLE 4. 10 RESPONSE TO QUESTION 15

Methotrexate is used to treat which of the following conditions? (tick all that apply)		
Answer Options	Response (n=85)	Answer
Osteomalacia	1 (1.2%)	Incorrect
Rheumatoid Arthritis	85 (100%)	Correct
Psoriatic Arthritis	83 (97.6%)	Correct
Vasculitis	43 (50.6%)	Correct

Question 15 was well answered, with only one incorrect response. Osteomalacia is a vitamin D deficiency, whereas Rheumatoid Arthritis, Psoriatic Arthritis and Vasculitis are all autoimmune diseases which can respond to Methotrexate treatment.

TABLE 4. 11 RESPONSE TO QUESTION 16

A 61-year-old man with RA for seven years is going on holiday. He normally takes Methotrexate 20mg weekly, folic acid 5mg weekly and atenolol 50mg for hypertension. Which of the following vaccinations should this patient NOT have? (Tick all that apply)		
Answer Options	Response (n=85)	Answer
Flu vaccination	1 (1.2%)	Incorrect
Tetanus	2 (2.4%)	Incorrect
Yellow Fever	85 (100%)	Correct
All of the above	0 (0%)	Incorrect

Question 16 was also well answered. Yellow fever is a live vaccination and could cause illness in a patient who is immune-compromised with a drug such as Methotrexate (Perry, Winthrop et al. 2014).

TABLE 4. 12 RESPONSE TO QUESTION 17

A 45-year-old lady with RA for seven years arrives at clinic complaining that she has been very breathless for the last couple of days. She has been taking her treatment as usual which comprises Methotrexate 15mg weekly, folic acid 5mg weekly, Sulfasalazine 2G daily and Cocodamol PRN. Do you:		
Answer Options	Response (n=84)	Answer
Tell her to go to her GP as you suspect a chest infection	10 (11.9%)	Incorrect
Tell her to increase her folic acid	0 (0%)	Incorrect
Stop the drugs and refer to a Rheumatologist	74 (88.1%)	Correct
Tell her not to worry as this is normal whilst on Methotrexate	0 (0%)	Incorrect

Question 17 was correctly answered by 88.1% (n=74) of the respondents. Methotrexate can cause pneumonitis (Ledingham, Gullick et al. 2017) and sudden breathlessness needs to be investigated. Whilst breathlessness could result from a chest infection, the correct course of action would be to stop drugs and investigate the breathless to ensure the correct treatment is given.

TABLE 4. 13 RESPONSE TO QUESTION 18

A 72-year-old with RA for 22 years is normally treated with Methotrexate 20mg weekly, folic acid 5mg daily, Ramipril 2.5mg daily and Atorvastatin. She is about to start antibiotics for cellulitis. Which of the following antibiotics should she avoid?		
Answer Options	Response (n=84)	Answer
Amoxycillin	5 (6%)	Incorrect
Erythromycin	1 (1.2%)	Incorrect
Flucloxacillin	0 (0%)	Incorrect
Trimethoprim	78 (92.9%)	Correct

The response to question 18 was correctly answered by most respondents, 92.9% (n=78). There are few drug interactions associated with Methotrexate (Bourré-Tessier and Haraoui 2010), but Trimethoprim can cause bone marrow suppression (Rushworth, Mathews et al. 2015) and as Methotrexate also has bone marrow suppressive effects, a combination of both could lead to significant bone marrow toxicity (Rushworth, Mathews et al. 2015).

TABLE 4. 14 RESPONSE TO QUESTION 19

A 76-year-old lady with RA for 15 years normally treated with Methotrexate 20mg weekly, folic acid 5mg daily, Bendroflumethiazide 2.5mg daily and Atorvastatin, has suspected pyelonephritis and is to start treatment with Kefalexin. What advice would you give regarding the Methotrexate?		
Answer Options	Response (n=84)	Answer
Carry on taking the Methotrexate but drink more water	9 (10.7%)	Incorrect
Reduce the dose of Methotrexate until the infection has cleared	0 (0%)	Incorrect
Increase the dose of folic acid	0 (0%)	Incorrect
Stop the Methotrexate until the infection has cleared	75 (89.3%)	Correct

89.3% (n=75) of respondents answered this question correctly. Whilst drinking water can help to alleviate the symptoms of pyelonephritis, a patient taking Methotrexate is more at

risk of developing a serious infection as they are immuno-suppressed which means that their immune systems are less effective at combatting infections(Ibrahim, Ahmed et al. 2019, Furer, Rondaan et al. 2020).

TABLE 4. 15 RESPONSE TO QUESTION 20

A previously fit 60-year-old man with recently diagnosed RA is to start combination treatment with Methotrexate and Hydroxychloroquine. He asks you whether he can continue to drink alcohol when he commences Methotrexate. Do you advise him:		
Answer Options	Response (n=84)	Answer
That it is safe to drink	0 (0%)	Incorrect
That he should not drink any alcohol	8 (9.5%)	Incorrect
To keep to the Government's recommended amount of 21 units per week	34 (40.5%)	Correct
To limit his alcohol intake to no more than 4 units per week	42 (50%)	Correct

The responses to question 20 posed mixed results, 40.5% (n=34) of respondents thought the limit of alcohol intake for patients taking Methotrexate should be the Government recommendation, whilst 50% (n=42) of respondents thought it should be no more than four units per week. The confusion over this question arose because the American College of Rheumatology recommends a limited intake of alcohol to four units per week, but the British Society of Rheumatology consider that the Government guidelines are sufficient (Price, James et al. 2010). As it was unclear which guideline was adopted in the Rheumatology unit in which the respondent worked, both of these responses were considered correct.

TABLE 4. 16 RESPONSE TO QUESTION 21

A 25 year-old woman has a three year history of RA treated with Methotrexate 15mg weekly, Sulfasalazine 2G daily and folic acid 5mg weekly. She and her partner wish to try for a family. For how long should the patient stop Methotrexate before attempting to conceive?		Answer
Answer Options	Response (n=83)	
2 weeks	0 (0%)	Incorrect
2 months	0 (0%)	Incorrect
3 months	42 (50.6%)	Correct
6 months	41 (49.4%)	Correct

This question also generated a definite split in responses. Methotrexate can be harmful to a foetus (Gromnica-Ihle and Kruger 2010) therefore it is recommended that it should be stopped for 3 months to allow it to clear from the system before a woman attempts to conceive (Gerosa, Schioppo et al. 2016). However some studies recommend stopping Methotrexate for six months prior to attempting to conceive (Lloyd, Carr et al. 1999). As it was impossible to determine whether the local guidelines around Methotrexate and pregnancy stated that patients should stop at six months or three months, both answers were considered correct.

TABLE 4. 17 RESPONSE TO QUESTION 22

A 30 year-old man with RA for 6 years treated with Methotrexate 20mg weekly and folic Acid 5mg weekly mentions that he and his partner have decided to start a family. He asks whether there is any advice with respect to taking his Methotrexate while they are trying to conceive. What do you advise?		
Answer Options	Response (n=83)	Answer
No specific action regarding his treatment is required	3 (3.6%)	Incorrect
He should stop the Methotrexate for two weeks prior to them trying to conceive	0 (0%)	Incorrect
He should stop the Methotrexate for two months prior to them trying to conceive	2 (2.4%)	Incorrect
He should stop the Methotrexate for three months prior to them trying to conceive	46 (55.4%)	Correct
He should stop the Methotrexate for six months prior to them trying to conceive	32 (38.6%)	Correct

The same confusion around the length of time a patient should stop Methotrexate prior to conception arose with question 22, 55.4% (n=46) responded that it should be three months and 38.6% (n=32) thought it should be six months. Whilst, as question 21, some literature recommends that a man should stop Methotrexate for three months prior to attempting to conceive, the evidence around this remains unclear (Gutierrez and Hwang 2017). Therefore, it was impossible to determine how far local guidelines in Rheumatology departments may have affected the responses. In order to account for this, both responses were considered correct.

TABLE 4. 18 RESPONSE TO QUESTION 23

A 36-year-old woman has had RA for five years. She is currently treated with oral Prednisolone 5mg daily, Methotrexate 20mg weekly, Sulfasalazine 2G daily and folic acid 5mg weekly. She attends your monitoring clinic concerned that she has been told by her GP that she has shingles affecting her left upper limb. State whether each of the following items is true or false.				Answer
Answer Options	True	False	n=	
Anyone can catch shingles from an infected person	34 (41.5%)	48 (58.5%)	82	False
People are at risk of developing chicken pox from contact with a person who has shingles	47 (57.3%)	35 (42.6%)	82	True
A person with a past history of chicken pox is unlikely to catch shingles from an infected person	28 (34.5%)	53 (65.4%)	81	True
Shingles can be more severe in patients taking Methotrexate and steroids	82 (98.7%)	1 (1.2%)	83	True
Chicken pox can be more severe in patients taking Methotrexate and steroids	78 (93.9%)	5 (6%)	83	True

Varicella is the virus which causes chicken pox (Gould 2014) and Methotrexate has been considered as a risk factor for the reactivation of varicella zoster, which causes shingles (McLean-Tooke, Aldridge et al. 2009). Adults who develop varicella can have more severe infections and can develop complications (Gould 2014). Because of the immuno-suppressant effects of Methotrexate, previously discussed, it is important that patients stop Methotrexate if they have active disease. The responses to this question revealed much confusion around shingles and chicken pox. 41.5% (n=34) of respondents did not know the answer to the first part of the question around who could develop shingles from an infected person. The responses to the second part of the question were fairly evenly split between true or false. The correct response was “true”, that people are at risk of developing chicken pox from someone who has shingles, if they have not had chicken pox before (Gould 2014). 65.4% of respondents gave an incorrect response to “a person with a past history of chicken pox is unlikely to catch shingles from an infected person”, the correct answer is “true”.

Shingles is not a disease that can be “caught”, it is reactivated in a person who has already had chicken pox and this reactivation can be cause as a result of stress or low immune response (Wilson 2014).

TABLE 4. 19 RESPONSE TO QUESTION 24

	Hb 13-18	WCC 4-11	Plat 150-400	MCV 80-96	ALT 5-35	APhos 45-105	Bilirubin 1-22	Alb 37-49	ESR 0-20
June 1st	13.2	5.4	212	85	56	46	21	35	25
July 1st	12.9	5.8	256	87	85	50	14	39	28
Aug 1st	13.0	5.2	220	84	140	96	17	34	30

A 56-year-old man with a 10-year history of RA attends the monitoring clinic. He is taking Methotrexate s/c 15mg weekly, folic acid 5mg 6 times a week, Hydroxychloroquine 200mg daily, Naproxen 250mg four times daily and Atenolol 50mg daily. His blood tests for the last 3 months are shown above. Which drug is most likely to be a cause of the abnormality which has developed in the patient’s results?

Answer Options	Response (n=83)	Answer
Methotrexate	66 (79.5%)	Correct
Hydroxychloroquine	1 (1.2%)	Incorrect
Naproxen	15 (18.1%)	Incorrect
Atenolol	1 (1.2%)	Incorrect
Folic acid	0 (0%)	Incorrect

79.5% (n=66) of respondents answered question 24 correctly, and almost 20% of the population were incorrect, with 18.1% (n=15) of respondents favouring naproxen as the correct answer. Methotrexate is known to be associated with liver toxicity (Conway and Carey 2017). However dose regulation and regular blood monitoring for signs of potential problems such as raised liver enzymes, Alkaline Phosphatase (APhos) and Alanine Aminotransferase (ALT) (Smolen, Landewé et al. 2017). Thus, recognising early signs of possible liver toxicity is an important role for the Rheumatology Specialist nurse.

TABLE 4. 20 RESPONSE TO QUESTION 25

	Hb 13-18	WCC 4-11	Plat 150-400	MCV 80-96	ALT 5-35	APhos 45-105	Bilirubin 1-22	Alb 37-49	ESR 0-20
June 1st	13.2	5.4	212	82	35	15	21	36	25
July 1st	11.9	5.8	350	70	45	36	14	39	28
Aug 1st	10.0	5.2	436	65	37	42	17	37	30

A 56 year-old man with a 10 year history of RA attends the monitoring clinic. He is taking Methotrexate s/c 15mg weekly, folic acid 5mg 6 times a week, Hydroxychloroquine 200mg daily, Naproxen 250mg four times daily and Atenolol 50mg daily. His blood tests for the last 3 months are shown above. Which drug is most likely to be a cause of the abnormality which has developed in the patient's results?

Answer Options	Responses (n=78)	Answer
Methotrexate	24 (30.8%)	Incorrect
Hydroxychloroquine	4 (5.1%)	Incorrect
Naproxen	47 (60.3%)	Correct
Atenolol	1 (1.3%)	Incorrect
Folic acid	2 (2.6%)	Incorrect

60.3% (n=47) correctly responded to question 24, however almost 40% of the respondents answered this incorrectly. Naproxen is a Non-Steroidal Anti-Inflammatory Drug (NSAID) which can inhibit the clotting mechanism of platelets leading to the risk of bleeding (Crofford 2013). Therefore, if patients are taking NSAIDs such as naproxen, it is important to monitor levels of haemoglobin (Hb) as if levels fall it could indicate bleeding. In this scenario, the Hb has slowly been decreasing and whilst it is impossible to determine whether the cause of this is bleeding, the correct course of action is to stop the Naproxen and initiate investigations.

TABLE 4. 21 RESPONSE TO QUESTION 26

Leucocytes	Protein	Nitrites	Glucose
++	Trace	Positive	Negative
A 76 year-old woman with longstanding RA attends clinic. Her treatment comprises Methotrexate 10mg weekly, folic acid 5mg weekly, Simvastatin 40mg daily and Ramipril 5mg daily. Urine dipstick test is shown above. What course of action would you take?			
Answer Options		Responses (n=77)	Answer
Arrange a mid-stream urine test		63 (81.8%)	Correct
Stop Methotrexate		2 (2.6%)	Incorrect
Start Amoxicillin		0 (0%)	Incorrect
Refer to patient's GP		6 (7.8%)	Incorrect
Refer to Rheumatologist		6 (7.8%)	Incorrect

81.8% (n=63) of respondents gave the correct answer to this final question, with almost 20% giving the wrong answers. Urinary tract infections are common, and recognising the signs are important for patients taking Methotrexate. In this scenario the patient presents with moderately positive leucocytes, a trace of protein and positive nitrites in a urine dipstick test. This is a test which can be comprises of a reagent strip designed to test markers of infection in a urine sample (Najeeb, Munir et al. 2015). The correct course of action in this scenario is to arrange a more accurate laboratory test to investigate whether the patient has an infection as the dipstick test in this scenario only indicates possible mild infection and therefore stopping the Methotrexate at this stage is not indicated.

4.8.6 Correlations with confidence and knowledge

Confidence was recorded on a four-point scale, not at all confident; somewhat confident; confident; very confident, and knowledge was assessed by the total each participant scored on the clinical knowledge questions. As described in section 4.5 of this chapter, Pearsons correlations and p-values were calculated. Confidence and knowledge correlated weakly positively (r=0.21) but the p-value showed statistical significance (p=0.05 n=85). The Pearsons calculation weakly correlated confidence with the amount of training received

(r=0.24) but the p-value showed a stronger degree of significance between those two variables (p=0.013, n=85) but there was no correlation between the time that it took to become confident and the amount of training received. The correlations are shown in Table 4.22.

TABLE 4. 22 PEARSON CORRELATIONS BETWEEN CONFIDENCE, KNOWLEDGE AND OTHER ASPECTS OF TRAINING

	Confidence	Knowledge	Amount of Training	Time in Education Role	Time to become Confident
Knowledge	0.21288*				
Amount of Training	0.24164*	0.01655		0.13999	-0.09154
Time in Education Role	0.7425***	0.11293	0.16507		0.17224
Time to become Confident	-0.00428	0.07166	-0.09154	0.74252	

*p<0.05 *** P=0.00001

The strongest correlation was between confidence and the time spent in the educational role (r=0.7425 p=0.00001 n=85). The Pearsons correlation showed a weak, non-significant relationship between the amount the Methotrexate educational interaction changed with time and the time it took the nurse to become confident (r= 0.35) but the p-value showed a much stronger statistical significance between the two variables (p=.0006 n=85). Further correlation between the year the participant qualified and their level of confidence showed a weak negative relationship (r-0.32) but the p-value demonstrated a higher degree of statistical significance (p=.0022 n=85). Thus, the longer the participant was qualified and the longer they had been performing the role, the more confident they were. Knowledge correlated with confidence as above, but did not correlate with the amount or helpfulness of training, or the time it took respondents to become confident. The amount of training

received weakly positively correlated with the participants' perception of how helpful it was (r= 0.37) but the p=value demonstrated a higher degree of statistical significance (p= .0006 n=85).

Of the nine participants who did not complete all of the knowledge questions, five respondents answered they were very confident in this role, one was confident, one somewhat confident and two not at all confident of which one did not attempt any knowledge questions.

4.9 Summary of the Findings

The domains of the survey focussed on four areas; training, confidence, time to become confident and knowledge. Eighty-seven respondents answered questions on if they had any training, and most respondents described having had some training (70% n=61) whilst 15% (n=12) had no training but 16% (n=14) had a lot of training. The responses to the type of training most nurses had (n=73) was largely observational, ie, they were observing peers (67% n=49) or Consultant Rheumatologists (11% n=8) whilst a small proportion of respondents had undertaken in-house courses on chemotherapy (9.5% n=7) and competencies (5.5% n=4). Fewer respondents had undertaken a structured Rheumatology course (5.5% n=4) and one respondent had undertaken a prescribing course. Seventy-six valid responses were received for a question around helpfulness of training and most respondents agreed that any training they had, was generally helpful, 50% (n=38) considered it very helpful, 22.4% (n=20) thought their training had been moderately helpful, 26.3% (n=20) of the respondents thought it was of some help whilst only one person thought it was of no help at all. When asked what type of training nurses should have, almost all responses agreed that communication skills, consultation skills, knowledge and experience were required, only one respondent thought that they were not necessary apart from experience.

Most respondents were either very confident or confident in their role of giving information about Methotrexate to patients. Out of the total number of valid responses (n=85) 12% (n=10) where somewhat confident and 5% (n=4) were not confident at all. But most respondents agreed that the way they give information had changed over time, and only

9.4% (n=8) of the valid responses (n=85) considered that it had not changed at all. 84 responses were received when asked how long it took to become confident, 13% (n=11) confident in zero - two months, and the remaining responses indicated that it took between three months to one year to become confident in the role.

Most nurses used information leaflets to support them during their consultations, 85 valid responses were received and 87.1% (n=74) used the Methotrexate information leaflets now produced by Versus Arthritis (2019). A substantial number of respondents used their own in-house leaflets (48.2% n=41) and the National Rheumatoid Arthritis Society (NRAS) leaflet on Methotrexate was also popular (25.9% n=22). Only 5.9% (n=5) of the valid responses (n=85) considered that these materials were only a little useful, and no-one thought they were not useful at all, the majority of responses agreed that written materials were useful support.

Knowledge was assessed by describing scenarios which could be encountered by the respondents and described in this chapter in section 4.2.1. Most respondents answered correctly to all questions, there were 90-100% accurate responses to questions about vaccinations, antibiotics and liver function. Questions on alcohol had a mixed response, 40.5% (n=34) of responders thought 21 units of alcohol per week was acceptable and 50% (n=42) thought the limit was four units. A question on shingles was not well answered with a range of responses. with regard to a question about pregnancy for a woman, opinion was divided between stopping Methotrexate for three months or six months; this likely reflects local Trust protocols and changing national guidelines. 19 respondents completed only the first half of the survey and a further eight respondents did not complete all of the single best answer questions.

4.10 Discussion

This phase of the study identified great variation in the training for this educational role and an appetite for more education including the need for consultation skill training. The role of the nurse in Rheumatology has changed considerably over the last 20 years (Oliver and Leary 2012). This role has evolved as a result of changing treatments in Rheumatology and service provision, but the investment into the training of nurses in this role has often been

overlooked (Oliver and Leary 2012). Whilst it is clear that nurses are extremely motivated and will seek out their own information, this survey has shown there is little accredited and standardised training for nurses in Rheumatology regarding the education of patients on Methotrexate. Interestingly, a questionnaire study by Courtney et al (2008) of the training of nurse prescribers in Diabetes showed that 23% of the nurses who completed the questionnaire had only had informal training involving observing a Specialist Nurse or doctor and 20% had no specialist training in diabetes at all. Further, of those respondents who had academic training almost half felt that their needs were not met with regards to the principles of diabetes prescribing. It seems that the lack of training for nurses undertaking a variety of role extended tasks is not specific to Rheumatology, and that this is a much more widespread issue.

There could be prohibiting factors involved in the lack of training for nurses. For example, Nurses often find it difficult to get time and funding for any training (Haywood, Pain et al. 2013). A recent survey by the Primary Care Respiratory Society UK (PCRSUK 2015) on nurse education, concluded "nurses will need to be increasingly more resourceful and self-motivated to access training and look beyond traditional study days using innovative methods such as online study and development recording". Courses where nurses can access training at a time that suits them and gain credits for completion may be popular. In this context, e-learning modules with associated assessment would seem to hold considerable potential. The results suggest that a module which contains the knowledge base required for the role, including advice on how to aid patient understanding effectively and contains answers to frequently asked questions, would be a useful addition to practical experience and may shorten the time to achieve confidence and competence.

The observation that confidence was most closely associated with time in the role suggests that experience leads to confidence. Nurses are learning as they work and the challenge is to shorten the time required to become confident with appropriate training and knowledge. The correlations with knowledge and amount of training suggest that it should be possible to increase confidence with better training. It is reassuring however, that confidence and knowledge did correlate. The New World Kirkpatrick Model (2006) has become one of the worldwide standards for evaluating the effectiveness of training and it describes the process of behavioural change as a result of knowledge. It is based on the four levels of training

evaluation which was developed by Dr Don Kirkpatrick in the 1950's (Kirkpatrick and Kirkpatrick 2016). The first level, reaction is the degree to which learners find their training favourable, engaging and relevant, the second level, learning, is the degree of knowledge, skills attitudes confidence and commitment that learners acquire which is based on their participation in the training. Behaviour, the third level relates to the degree to which learners apply what they have learned during the training process and lastly results, relate to the targeted outcomes of that training. These four levels could be applied as best practice to the processes of teaching patients about Methotrexate: Reaction, where patients need to be engaged and find the information understandable and relevant; learning, where the evaluation by the nurse to establish how much knowledge the patient has acquired during that teaching process; behaviour, whether the patient take the medication as prescribed and would they feedback any problems or issues to the nurse and results, whether patients feel empowered to communicate to the nurse that they have side effects, cannot take their medication as prescribed and have enough understanding of Methotrexate to identify other potentially dangerous problems and report them to the healthcare professional.

4.11 Limitations of the Survey

It is not possible to know if the sample of 104 nurses who started this survey is typical of nurses who perform this role, but the numbers include specialist, monitoring and research nurses who are the people likely to perform this role. It has also included a wide variety of experience and views. It is likely that the participants are more interested and informed than average but it also includes people who were not sufficiently confident to complete the knowledge questions. Eighty-five participants started the knowledge questions but only 77 participants completed the entire questionnaire. It could be speculated that participants could have been intimidated by the knowledge questions and chose to close the questionnaire. However, the survey's assessment of knowledge was rudimentary and brief, and was clearly not long enough to make a reliable judgement of respondents' knowledge. Nevertheless, it did serve to give some indication of respondents' understanding of the area as it applies to clinical practice. It may also serve to promote discussion of the assessment of this important area of practice. Involvement of patients in the design of the questionnaire may have raised different types of concern.

4.12 Chapter 4 Conclusion

This Chapter has described the first phase of the study, the national survey. It has explained how the survey was designed, how the survey was distributed to gain as many responses possible on a national level, and how nurses who give information to patients about Methotrexate are trained to conduct this role. It also described whether they regarded their training as helpful and determined whether it is important to have skills required to conduct this role. It also described how confident nurses are in conducting this role and how long it takes for them to become confident. Further, this chapter explained the responses to knowledge questions based on possible scenarios which could be encountered by the nurses. The nurses included in this survey showed a great variation in the training they had prior to undertaking the role of counselling patients starting Methotrexate, with those nurses performing the role for the longest period of time having the least training. Most respondents took three to 12 months to feel confident in this role but even the most confident nurses continued to change the way they educated patients with increasing experience and knowledge. Most respondents answered that they would have liked more training aimed at satisfying the educational needs of nurses to counsel patients about drugs like Methotrexate which could lead to nurses gaining knowledge and confidence with this role and be able to deliver a competent and comprehensive educational interaction with patients.

The current understanding of how nurses are trained to carry out the role of advising patients about Methotrexate is limited, most researchers concentrate on the value of the Rheumatology Specialist nurse in conducting consultations rather than how they gained the knowledge to carry out this role and how they interact with the patient during this process (Hill 1997, Koksvik, Hagen et al. 2013, Garner, Lopatina et al. 2017). The results of this survey have provided a general perspective on how nurses gain knowledge about Methotrexate in order to instruct patients on how to take it safely and as prescribed. It has shown that most nurses rely on information booklets which are generally developed for patients but they do become confident in this role after a period of time.

The next phase of the study, Phase II, aimed to explore the experiences of nurses and their perception of how they delivered information about Methotrexate to patients through semi-structured interviews. The contribution of Phase I, the national questionnaire survey,

to Phase II was to inform the semi-structured interview schedule. Phase I identified that nurses who responded to the questionnaire generally observed peers and doctors to become informed about how to give information to patients about Methotrexate, that they used written information to support theses consultations and that they became confident to conduct this role over time. It also showed that these nurses were generally knowledgeable and would respond appropriately in specific scenarios. Thus, the interview schedule was designed to determine how individual nurses were trained to carry out their role and how they felt about this training; how they used the information leaflets to inform their consultations. Phase II of the study investigated, in more depth, how nurses feel about conducting their role and how confident they are. What was not clear in Phase I, was how nurses interacted with patients, and whether they recognised cues and responses from patients putting them at the centre of care.

Chapter 5: Phase II - An exploration of the experiences of Rheumatology Specialist nurses counselling patients on Methotrexate therapy

5.1 Introduction

5.1.2 Summary of Phase I results

The domains of the survey in Phase I focussed on four main areas, training, confidence, time to become confident and knowledge. Not all respondents completed all of the questions, but of the valid responses received, most nurses were trained to carry out the role of giving information to patients about Methotrexate, by observing peers and Rheumatology consultants. Most respondents used the Methotrexate information booklet produced by Versus Arthritis (Versus Arthritis 2019) and information produced in-house to support this process during their consultations. Most nurses became confident to carry out this function within three to six months. Knowledge was assessed by multiple choice answers to clinical scenarios which would commonly be experienced by the nurses. Most respondents answered the knowledge questions correctly, but there were areas of confusion around the amount of time a patient should stop taking Methotrexate prior to pregnancy. However this confusion could have arisen because, whilst most publications recommend that males and females should stop Methotrexate three months prior to pregnancy, there is no clear recommendation (Gutierrez and Hwang 2017). Therefore, different protocols which guide clinical practice in different Rheumatology services may be different. Another question which caused a range of mixed responses were questions on shingles. For example, almost half of the respondents incorrectly answered that people with a past history of chicken pox could catch shingles from an infected person. Shingles is the result of reactivation of the herpes zoster virus in the body of some who has previously had chicken pox and cannot be caught from anyone else (Gould 2014).

Whilst it appeared from the results of the survey that nurses were confident at conducting their role and used information booklets to guide their consultations with patients, it was

not clear how the nurses felt about their practice, how far the booklets guided their consultations and how nurses perceive the patient's role in this process. Therefore, Phase II of the study attempted to fill in these gaps by exploring the nurses' feelings about their roles and how they were educated to conduct it. Also, to investigate how the information booklets are used, and how much reliance there is on these sources of information and whether patients have an active role in this process putting them at the centre of care so that they understand how to take Methotrexate safely and as prescribed.

This Chapter contains an explanation of the analysis methods adopted to explore the data generated by this study and describes the findings and themes generated through thematic analysis. It also contains a summary of the results based on the themes and closes with a brief discussion of areas for further consideration, as this will be discussed more thoroughly in Chapter 7.

5.1.3 Methotrexate Education for Patients

The commencement of any medication should be accompanied by some education to enable the patient to know how to take it, how and when it is expected to work, what side effects to look out for and what, if any, the safety blood monitoring which is required. Hill et al (2001) demonstrated that educating Rheumatology patients on their medication improved concordance. Zhao et al (2015) carried out a survey of 159 patients with Coronary Heart Disease (CHD) in a hospital in China. They assessed medication adherence with the Morisky Medication Adherence Scale (Morisky, Green et al. 1986) and disease knowledge with a Medicine/Disease Related Knowledge Test (MDKRT). The MDKRT was developed by the researchers with guidance from an expert panel and a systematic literature review (Al Hamarneh, Crealey et al. 2011). Zhao et al (2015)concluded that whilst the majority of participants had little knowledge of drug treatment, those participants that had a greater knowledge of CDH were more likely to be drug adherent. Despite the paucity of evidence, guidelines uniformly recommend education (NICE 2013) and the Department of Health (2019) advocates that health professionals promote self-care and shared decision-making, enabling patients to make choices. This would require the patient to be sufficiently educated, which, in the case of commencing Methotrexate, commonly is dependent upon

education by nurses who may not necessarily have received education themselves in this area.

Patients also require information on their condition to put the treatment into context (Thompson 2011). Thompson conducted a study of patients with Ankylosing Spondylitis, and found that at disease presentation, before drug therapy was commenced, patients wanted responses to a series of questions which included: 'Why have I got it?' 'What will happen to me and my family?' What can I do about it?' Nurses need training to allow them to develop the skills to engage in effective consultations with the patients and to increase their confidence in moving away from a checklist consultation. Phase II of this study aimed at exploring the experiences of Rheumatology Specialist nurses of their consultations with patients when giving information about Methotrexate. Thus, further insights into how nurses perceived this process of information giving could be gleaned, adding to the body of extant literature.

It is not obvious from a review of extant literature that any studies have been conducted concerning how Rheumatology Specialist nurses are taught to carry out specialist roles. Latter et al (2001) recognized that nurses make an important contribution to the education of patients, and carried out a survey of student nurses to identify drug knowledge and attitudes towards patient education, focusing on adult, older person, mental health and community programmes. They concluded that students expected to learn on the job in order to gain knowledge and experience. Therefore, this underlying expectation of learning on the job in order to gain knowledge and experience may well contribute to the lack of formal education nurses seek when developing their careers. Dury et al (2014) recognize that Specialist nurses evolved to meet healthcare needs and the changing context of nursing care. They therefore developed an online questionnaire to explore the competencies and educational requirements of these nurses. However, this was a widely diverse study which involved 77 nurses from 29 countries across Europe and most of those nurses had undertaken postgraduate or advanced courses and held posts such as Chief Nurses, Nursing Administrators or Advance Practitioners, so they are not necessarily representative of the general Specialist nurse. However, even from that very specific population (n=77), 13 had no Specialist nurse training. Jokiniemi et al (2020) carried out ten semi-structured in order

to identify the domains of practice of Specialist nurses and their competencies. Nurse managers who had at least one Specialist nurse in their department were the target population. The nurse managers recognized 255 nurses in their departments whom they considered to be working as Specialist nurses in various clinical setting. They also recognized that these nurses were constantly seeking ways of improving themselves beyond their basic training, actively seeking evidence-based knowledge and educating themselves within their own specialist area. There was no discussion of any formal training to gain specialist skills to support their roles, it therefore appears that these nurses were also learning on the job. Further, the survey results from Phase I of this study, confirm that, of the nurses who responded to the survey, the primary source of training was learning from peers by observation.

5.2 Summary of Phase II

This phase of the study generated narrative qualitative data in response to open questions through face to face semi-structured interviews. The interviews explored the nurses' thoughts and feelings of a recalled interaction with a patient during a Methotrexate information giving process. The nurses worked in two different Rheumatology services and had different educational opportunities to gain more knowledge about Rheumatological conditions and treatment. The interviews were audio-recorded and transcribed. Data collected were exploratory and thematic analysis of the transcripts developed and categorised themes in order to explore how nurses gave information to patients about Methotrexate and whether interactions with the patients were part of the consultation process.

5.3 Phase II Aims and Objectives

5.3.1 Phase II Aim

To explore the nurse experience and perception of the delivery of information about Methotrexate to patients, using semi-structured interviews.

5.3.2 Phase II Objectives

1. To explore the training nurses had in order to carry out their role of giving information to patients on Methotrexate and how useful this was.
2. To understand how confident nurses are carrying out this role and how they feel about the training they had.
3. To understand how nurses, use written information to inform their consultations.
4. To explore how nurses, respond to patient cues putting them at the centre of care.

5.4 Method

5.4.1 Study Design

5.4.1.2 Semi-Structured Interviews

Semi-structured interviews are a common form of qualitative data collection (Kallio, Pietilä et al. 2016) attempting to discover what an individual thinks and feels about a subject and how significant it is to them (Mears 2012). Yet, regardless of how carefully questions are asked there is always a residue of ambiguity (Fontana and Frey 2005) making interviewing more complex than it sounds. The commonest form of interviewing is face to face, and it can be structured, semi-structured or unstructured. In structured interviews, all participants are asked the same question, usually with limited response categories and there is little room for manoeuvre. Semi-structured interviews use pre-set but open ended questions to allow further exploration of the topic with the interviewee, thus are widely employed by healthcare professionals (Jamshed 2014). Semi-structured interviews are particularly applicable where the researcher has more specific research questions (Low 2013). Thus, the rationale for using semi-structured interviews in Phase II of the study is because this form of interview allows the researcher to explore themes with the participant, but within the boundaries of the research question.

Semi-structured interviews are commonly utilised in qualitative research, particularly in

healthcare research (DeJonckheere and Vaughn 2019). DeJonckheere and Vaughn reviewed the literature on semi-structured interviewing in order to identify key skills and components required to implement this key technique. They recommend 11 key steps which they consider are required to design and conduct semi-structured interviews (Table 5.1)

TABLE 5. 1 STEPS TO DESIGNING AND CONDUCTING SEMI-STRUCTURED INTERVIEWS (DEJONCKHEERE AND VAUGHN 2019)

Step	Task
1.	Determine the purpose and scope of the study
2.	Identify participants
3.	Consider ethical issues
4.	Planning logistical aspects
5.	Develop the interview guide
6.	Establish trust and rapport
7.	Conducting the interview
8.	Memoing and reflection
9.	Analysing the data
10.	Demonstrating the trustworthiness of the research
11.	Presenting findings in a paper or report

Whilst the work by DeJonckheere and Vaughan (2019) was published after the semi-structured interview phase of the study presented in this thesis, the 11 key steps they describe above parallel the stages taken to design this second phase. The aims and objectives of Phase II were identified and sites were identified where potential participants could be recruited. Ethical approval was applied for and given before any study activities took place. The logistics of how Phase II would be carried out was identified and organised and an interview guide was developed. The researcher met the nurses who agreed to participate and established a friendly rapport before conducting the interviews. Notes were taken of the whole experience which contributed to the reflexive perspective of the researcher before data analysis began.

The final two steps are described in following sections of this chapter.

Whilst the goal of the semi-structured interviews was to gain a rich understanding of the nurses' experiences and perspectives about the way in which they deliver information to patients about Methotrexate, it could be considered ethically unsound to collect data which is not completely necessary for the research (Kallio, Pietilä et al. 2016). Further, in order to ensure that the researcher remained focussed and no topics are missed an interview guide was utilised (Mears 2012, Mitchell 2015). Following a systematic review, Kallio et al (2016) identified key domains to consider when developing an interview guide supporting the trustworthiness of the data. The first consideration is to ensure that semi-structured interviews are an appropriate form of data collected in relation to the research question. The use of semi-structured interviews for Phase II of the study presented in this thesis was considered an appropriate form of data collection in order to explore further the nurses' perspectives and experience of the phenomenon under study. Secondly, Kallio et al consider that it is necessary to gain an understanding of previous work conducted, which was undertaken in a literature review for this study. Thirdly, the interview guide should be based on previous knowledge. The first phase of the study presented in this thesis, collected data, the findings of which informed the semi-structured interviews in the second phase of the study. Previous work was also considered following a literature review. The next phase described by Kallio et al was to validate the structure of the semi-structured interview guide, this was undertaken for this study through peer review. The researcher discussed the semi-structured interview guide with colleagues and supervisors, to ensure validity and appropriateness of the final semi-structured interview guide.

5.5 Data Analysis

5.5.1 Transcript Analysis

There are a broad range of approaches to analysing transcript data from interviews, but essentially, the aim of the transcript analysis is to produce an organised and detailed account of the themes and topics which were addressed in the semi-structured interviews undertaken (Burnard 1991). Some common approaches were outlined by Green and Thorogood (2018)

which they describe as firstly developing conceptual definitions, secondly, developing typologies and classifications, thirdly to explore associations between attitudes, behaviours and experiences, leading to the development of explanations of phenomena. Finally concluding with the generation of new ideas and theories. One of the commonest approaches in healthcare settings is thematic analysis (Green and Thorogood 2018) and Braun and Clarke consider that it should be the first method of qualitative analysis that researchers should learn as it helps the researcher to develop core transferrable skills (Braun and Clarke 2006, Braun and Clarke 2012). It could then be considered a process which can be utilised within another established analytical tradition (Ryan and Bernard 2000). Braun and Clarke produced a six-phase outline of the process of thematic analysis (Table 5.2). This process was adopted to conduct the thematic analyses for this study and this process is further described in Chapter 6.

TABLE 5. 2 SIX PHASE OUTLINE OF THEMATIC ANALYSIS PROCESS (BRAUN AND CLARKE 2006)

Phase	Description of the process
Familiarisation	Data transcription, reading and re-reading, making notes
Coding	Systematically coding interesting features – collate data relevant to each code
Searching for Themes	Collating codes into themes - gather data into each theme
Reviewing Themes	Check to ensure the themes are relevant to coded extracts, generate a thematic map of the analysis
Definition of Themes	Clarify themes, generate clear definitions
Reporting	Select obvious and compelling extract examples to illustrate the themes and the research question

A qualitative phenomenological approach (Ritchie and Lewis 2003), was adopted in designing this phase of the study (see Chapter 3 for further discussion of Phenomenology) as it seeks to understand the experiences of a population which share similar features and how they make sense of those situations (Connell, McMahon et al. 2014). As the study

population were all qualified nurses, giving information to patients about Methotrexate in a consultation-style interaction, they shared similar features in that the salient information given about Methotrexate should be comparable. Thus a phenomenological approach was adopted in the thematic analysis of the interviews, as it seeks to understand the experiences of a population which share similar features and how they make sense of those experiences (Connell, McMahon et al. 2014). The process involves reading and re-reading the transcripts (Biggerstaff and Thompson 2008). Husserl (Husserl 1999) would advocate the suspension of critical judgement during this process whilst a Heiderggerian approach would embrace the researcher's own experiences in the examination of the transcripts enriching the resulting data (Pratt 2012). However, the researcher must also adopt a reflexive perspective, in order to understand their own preconceptions which may influence the outcomes. In this analysis, the researcher was able to understand their own preconceived ideas around the themes which could be drawn out of the transcripts. There was a presumption that the nurses would differ in their experience, confidence and knowledge, that the consultation process was not a core part of nurse training and experience. These preconceptions were the result of the researcher's own experiences carrying out the same role of conducting Methotrexate education consultations. In a Heiderggerian fashion, it could be said that this added to a deeper understanding of the nurses' perspectives and reflections as the researcher could relate to their experiences. However, having undertaken a reflexive position, the researcher was also able to take a more objective stance when analysing the semi-structured interviews.

Participants were identified for Phase II through known professional contacts in two NHS Trusts in England and were purposively sampled to ensure the greatest diversity of experience and training. Purposive sampling also allows identification of a group who will have a common understanding of the research question (Connell, McMahon et al. 2014). In Trust A, the nurses had set appointments to see patients in order to carry out the Methotrexate consultations, contrastingly the nurses in the Trust B had no pre-planned appointment slots, the patients were seen in their regular clinics with their Consultants, and they were given their education on the same day if they were prescribed Methotrexate. This meant that the nurses did not know how many patients they would see in any given day and they had to fit it in around their regular work. It did mean, however, that patients did not have to wait several weeks for the next appointment and could start their treatment immediately. The nurses who worked in

Trust A also had access to a Rheumatology MSc Course which was run by the University attached to the Trust, the nurses at Trust B had no access to any training, they learned on the job. The interview schedule was based on the results of the national survey.

5.5.2 Use of Interviews to explore nurses' perceptions about their role

Semi-structured interviews allow participants to share their experiences within the boundaries of the topic under study (Mitchell 2015). The studies reviewed below use interviews to explore nurses' experiences. Whilst they are not focused on Rheumatology, they use semi-structured interviews to explore how nurses feel about aspects of their role, thus informing the decision to adopt semi-structured interviews as a method for Phase II.

Forsgren et al (2016) conducted a study to explore the experiences of eight nurses working with people who have communication disabilities in 6 different nursing homes. They constructed an interview guide addressing general communication and more specifically the experiences of the nurses communicating with residents who have communication difficulties. The questions related to four main areas; experiences communicating with residents, the nurses' feelings associated with interactions with residents who have communication disabilities, meaning related to these interactions and factors which influenced interactions. The study was limited to eight participants from six residential homes, and Forsgren et al (2016) explain that the number of participants was regarded as sufficient because the study did not aim to collect a representative view, but instead to contribute to the body of knowledge about important aspects of managing communication barriers.

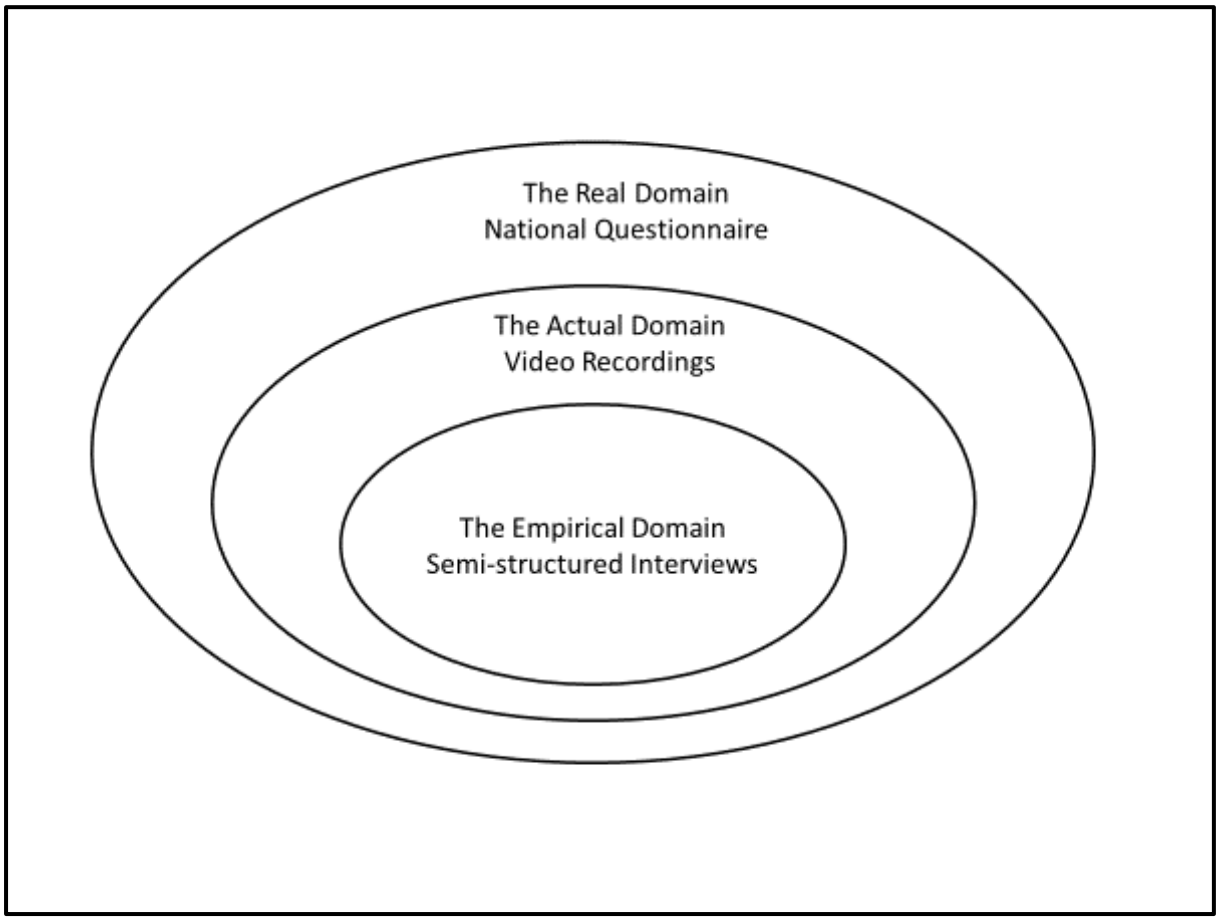
A study by Andersson et al (2016) explored nurses' experiences of caring for dying patients on surgical wards. They recognized that there was a lack of training in this area and this lack of preparation could lead to stress, anxiety and burnout. They interviewed six newly graduated nurses from two surgical wards and the interviews focused on six domains; care for palliative and curative patients, nursing skills, supporting activities, preparation for end-of-life situations, use of strategies and emotional aspects in nursing. The authors recognized

the limitations of the small number of interviews, but they considered that the trustworthiness of the results was ensured through a rigorous systematic analysis process.

Scrafton et al (2012) explored the experiences of nurses prescribers in secondary care, how nurse prescribing is employed and what they perceived the benefits and disadvantages to be. They focused on exploring the views of the nurses regarding how educationally prepared they were for this role, to explore their experiences in this role and to formulate some recommendations to inform practice. Six nurses were interviewed and audio-recorded. The authors considered that the sample size was in keeping with the recommended sample size for qualitative research (Sandelowski 1995).

The key features of these studies are that they all employ semi-structured interviews, they recognized that small sample sizes are appropriate for qualitative research and whilst the findings do not represent a general population, they can inform the extant body of literature. Further features of these studies identified key areas for the interview schedule, exploration of feelings, confidence and experiences. These key features contributed to the development of Phase II, representing the empirical domain of the philosophical critical realism perspective which was undertaken by semi-structured interviews (Figure 5.1).

FIGURE 5. 1 INVESTIGATION OF THE EMPIRICAL DOMAIN – SEMI-STRUCTURED INTERVIEWS



Thus, the semi-structured interviews explored in more detail the nurses' feelings and perceptions of how they engage with patients whilst giving information about Methotrexate.

5.5.2.1 Interview Design

The interview schedule (Figure 5.2) was developed by the researcher and a steering group (which consisted of two Rheumatologists, two nurses and an academic psychologist) who have expertise in this area was formed to further review the interview schedule. The results of the survey informed the topic guide.

FIGURE 5. 2 THE INTERVIEW SCHEDULE

Nurse Interview Schedule

1. Can you describe a recent education session?
   - Do the sessions vary?
   - If they do, in what ways do they vary?

2. Do you use any written information or prompts?
   - Can you describe what you use?

3. Are there some key areas you try to cover when educating patients?
   - Can you describe these?

4. Do patients express their views during these sessions?
   - What are their views?
   - What sort of things do patients talk about?

5. Do you have adequate time to do the education sessions?
   - How much time does it normally take?
   -

6. After the education sessions, do you monitor these patients yourself?
   - How does the monitoring/follow up system work in your department?

7. What preparation did you have before you started educating patients starting Methotrexate?
   - Did you have any supervised practice?
   - What did it consist of?
   - How useful did you find it?

8. In an ideal world what training would you like?

9. How do you feel now about educating patients starting Methotrexate?
   - How confident are you with this role?

Prior to commencement of the semi-structured interviews, all participants were invited to describe a recent education session that involved counselling a patient on Methotrexate. Their views and experience were sought on: written prompts used during the consultation; key information needed by the patient; patient engagement in the session; duration of the session; training received to counsel patients on Methotrexate and their confidence in counselling and planning for subsequent monitoring appointments. The interviews took place in a quiet room within the hospital in which the participants worked and lasted between 45 to 60 minutes. Interviews were recorded using a digital recorder and

transcribed verbatim by an experienced transcriber and described in section 5.12 of this chapter.

5.6 Ethical Approval

Ethical Approval was applied for at the same time as Phase I of this study, and was obtained from the NRES Committee North East – Sunderland in 2013 (see Appendix 8). Approval was also given by Northumbria Healthcare Foundation Trust on 09/07/2013 to act as study Sponsor (see Appendix 9). A letter of invitation and study information was emailed to all participants. Informed consent was obtained prior to conducting the interviews.

5.7 Sampling Strategy

Semi-structured interviews were performed with a purposive sample of six nurses from two Rheumatology centres in the United Kingdom. The phenomenological method embraced to conduct this phase of the study, sought to understand the experiences of the interviewees, from a targeted population with similar key attributes (Eatough and Smith 2008). It is firstly important to consider the sampling technique to implement in a research study. Purposive sampling techniques are often used in qualitative research (Teddlie and Yu 2007) and can be defined as selecting units, ie groups or individuals, which have particular characteristics in common with the research question. Teddlie and Yu (2007) further describes purposive sampling to achieve representativeness or comparability; sampling special or unique cases; sequential sampling or sampling using multiple purposive techniques. Therefore, in applying purposive sampling to this phase of the study, it aimed at targeting nurses who had the same role of giving information about Methotrexate and may exhibit similar feelings and experiences. Secondly, the small sample size in this phase of the study is in keeping with comparable other qualitative studies where the objective is to gain an in-depth understanding of the experience of particular individuals through semi-structured interviews (Greenhalgh and Taylor 1997; Connell, et al 2014). Further, Polkinghorne (1989) recommends that between five to 25 individuals are required to develop the possibilities of experience using a phenomenological method (Creswell, Hanson et al. 2007).

5.8 Participants

The participants were identified by the researcher from two Rheumatology units in different areas of England. The only eligibility criteria required for participation was that the interviewees were involved in the education of patients about to commence Methotrexate. All eligible nurses from both units were invited to take part in the semi-structured interviews and any nurse who showed an interested was emailed information sheets (see Appendix 11) about the study. All potential participants had the opportunity to ask questions by email before they made a final decision on whether to participate. Three participants from each unit agreed to take part. Whilst none of these nurses had any formal training, two of them were waiting to start a course in Rheumatology which was administered by the local University. However, their training at the point of the semi-structured interviews were also by observing colleagues and learning on the job. Prior to signing the consent form, each participant was offered further opportunity to ask any more questions. Informed consent (see Appendix 11) was taken from each participant before the interview began. Participants were informed that the interview would be audio-recorded and that these recordings would be transcribed verbatim, however all data which could reveal their identity would be either removed or coded. Each participant was given a unique identification number which replaced their name in the final typed transcriptions. All participants were given the opportunity to check the final transcriptions before any analysis began, to ensure that they were satisfied that they had answered the questions in the way that they had intended. There was no pre-fixed time for each interview, but they lasted for between 30 – 60 minutes.

5.9 Interview Setting

The services offered by the individual units were different. In one unit, when a patient was prescribed Methotrexate by the Rheumatologist, they saw a nurse on the same day. The patient was fitted into the drug monitoring clinic and was given information about Methotrexate by one of the nurses working in that clinic on that day. A clinic room was used, but the time allocated to the consultation was not fixed. The amount of time spent on

this interaction would be dependent on how busy the monitoring clinic was at that time. In this service, there was no formal training undertaken by the nurses, they learned through experience and watching peers. In the second Rheumatology service, the patient was given an appointment to return to the department to see a nurse. The nurse was allocated 30 minutes per appointment to undertake the consultation with the patient.

5.10 Trustworthiness of the Data

Quantitative approaches would generally be used to answer questions requiring numerical data, which uses larger numbers to control for individual variations. Results can be judged in terms of reliability, ie consistency of the results; validity, ie accuracy and generalisability, ie the results can be applied to other situations (Leung 2015). Qualitative methods, on the other hand, explore human experience, recognising patterns in words and behaviour to generate a meaningful conclusion without losing the richness and dimensionality of that experience (Leung 2015). Qualitative methods can be considered as being subjective, therefore the interpretation of data could contain biases from both the participants and the researchers. This could in fact, add to the richness and depth of the data Lueng (2015). Indeed, bias exists in all study designs (Smith and Noble 2014), for example bias could exist in qualitative research such as a clinical trial, in the selection of participants. Whilst this can be reduced through random selection; participant drop out, or participants lost to follow up can change the characteristics of the participant group (Sica 2006). Minimising bias is one of the key considerations when designing a study and undertaking research allowing evaluation and scrutiny of the study findings (Smith and Noble 2014).

Defining standards for assessing qualitative research in order to judge the robustness of the data is important as it will enhance the transferability of the findings, but it should consider that the goal of the qualitative approach is to discover the natural order of the way things are. Making the assessment of the methods and results too rigid, may lead to losing that important and rich reflection of real-life situations. Quantitative research reliability relates on the replication of the research processes and results which can be assessed for validity, reliability and empirical generalisability (Kitto, Chesters et al. 2008). Applying these criteria to qualitative research is beset with difficulties due to the different types of data collection, design and

methods of study. Terms such as rigour, credibility and relevance are more applicable to qualitative research (Table 5.3).

TABLE 5. 3 RESEARCH TERMS (KITTO, CHESTERS ET AL. 2008)

Credibility: refers to whether the findings are well presented and meaningful
Evaluation rigour: the transparent description of ethical and political aspects of the conduct of the research
Procedural rigour: the transparent description of the conduct of the research
Reflexivity: open acknowledgement of the complex influences among the researchers, the research topic and subjects on the research results
Transferability or relevance: refers to how useful the findings are to the context and phenomenon under study
Triangulation: a comprehensive approach to the conduct of research using multiple theories data and methods

However, it could be argued that in order to explore and gain deep meaningful knowledge of some research questions multiple approaches should be adopted. A single method may limit the perspective and understanding of the research question.

Lincoln and Guba (1986) explain that the criteria used in the conventional and scientific model is the truth value or internal validity; applicability or generalizability; consistency or reliability and neutrality or objectivity. These four domains when fulfilled, remove any problems relating to bias, instability etc. However ontological, epistemological and methodological variations between different models may require the application of alternative criteria in order to meet the four domains. Therefore, they suggest that credibility as an alternative to internal validity, transferability as an alternative to external validity, dependability as an alternative to reliability and confirmability as an alternative to objectivity. They term these as criteria for trustworthiness. These criteria are still widely used and the aim of them is to state that the research findings are "worth paying attention to" (Elo, Kääriäinen et al. 2014). Baillie (2015) summarises these criteria in Table 5.4.

TABLE 5. 4 SUMMARY OF TRUSTWORTHINESS CRITERIA (BAILLIE 2015)

Traditional or quantitative criteria	Naturalistic or qualitative criteria	Explanation	Examples of techniques
Validity	Credibility	The findings make sense	Member checking Prolonged time in field Triangulation Peer debriefing
Reliability	Dependability	The research has been conducted in an auditable way	Audit trail of decision-making throughout the process
Generalisability	Transferability	Potential for findings to be transferred to another situation	Rich description of the setting and participants
Objectivity	Confirmability	Confirmation of the researcher's position and influence	Reflexivity – reflexive notes

5.11 Credibility of the Data

All of the semi-structured interviews were conducted in the same way using the interview guide, by the study researcher. Interviews were conducted in a quiet room, away from the clinical working area, so that the participant could feel comfortable and willing to share their experiences (Hove and Anda 2005). The audio-recorder was switched on before the interview began to allow time for the interviewee to become accustomed to it. The researcher introduced herself, giving a brief background to the study and explained the purpose of the interview, the participant was invited to chat about themselves to encourage a relaxed rapport, and was invited to ask any other questions before the interviews began. All interviews were allocated as much time as necessary for the participants to give their own responses to each question, the interviewer attempted not to interrupt the flow of the conversation from the interviewee during the process. At the end of the interview, the

researcher played the recording back to ensure that the recording was of good quality and informed the participant that they would receive an anonymised typed transcript for their confirmation of accuracy or to make changes or additions.

5.12 Data Transcription

The data transcription was undertaken by an experienced transcriber within the researcher's place of employment at Northumbria Healthcare NHS Foundation Trust. It was considered judicious to engage another person with experience to carry out this task. Further, the experienced transcriber could carry out this undertaking in a much timelier fashion. As the transcriber was experienced in this type of assignment, she understood her duty to uphold Northumbria Healthcare NHS Foundation Trust's policy of confidentiality. Further, the transcriber also worked within the same department as the researcher, and when queries occurred regarding the transcripts they were conveniently placed to have discussions. All identifiers such as name, place of employment or reference to other persons during the interview were removed by the transcriber. The recording was given to the transcriber as soon as each interview was complete, it was then transcribed and the transcription was checked against the recording to ensure accuracy by the researcher. All transcriptions were stored on a secure platform within Northumbria Healthcare NHS Foundation Trust secure IT system.

The transcript was returned to the participant as soon as it was complete to ensure that they were satisfied that anonymity had been upheld and that the data were accurate. All transcripts were returned to the interviewees within seven days to ensure they still had a recollection of the interviews. All participants had the opportunity to change or add to the transcripts if necessary. Further, participants were also asked if anonymous quotes could be used in this study and any prospective presentations and publications. All participants agreed and no changes were made to the transcriptions.

Immersion in the data is considered to be the first step of the analysis process (Green, Willis et al. 2007). Green et al also further discuss that the insights gained by the interviewer such as the context of the interviews including hesitations, confidence of interviewees in

responding to questions, shared experiences with the interviewees, all allow the interviewer to draw on this experience and contribute to the subsequent interpretation of the data. As the recordings were not transcribed by the interviewer, further immersion in the data was achieved by reading and re-reading the transcripts whilst listening to the recorded interviews. Data immersion allowed for a detailed examination of what the interviewees said and started the process of identifying themes and sub-themes, laying down the sub-structure for further analysis (Green, Willis et al. 2007). See section 5.16.2 below for further discussion of data immersion as part of the data analysis process of the Phase II semi-structured interviews.

5.13 Dependability

A study protocol (see Appendix 12) was developed in order to ensure that each step of the study was transparent and reproduceable. This protocol was reviewed by the Ethics Committee and approval given. Each step of conducting the study is clearly represented in the protocol and the researcher conducted the study in accordance with the protocol to ensure that consistency and reliability of the data were as robust as possible.

5.14 Transferability

Transferability refers to whether or not the study findings can be transferred to another similar context or situation (Houghton, Casey et al. 2013). Thick description is a strategy which is intended to determine transferability and the original context of the research should be comprehensively described so that judgements can be made (Koch 1994). It is therefore the researcher's responsibility to ensure that enough detail about the research and findings are described so that a reader can determine whether the outcomes can be transferred into their contexts. These details include accounts of the study context, the research methods employed and examples of raw data from which interpretations can be made (Dawson 2009).

5.15 Confirmability

Noble and Smith (2015) describe confirmability as centring on the acknowledgement of the complexity of the prolonged interaction with the participants in the study, and how the research methods used and outcomes are essentially linked to the researchers philosophical position, experiences and perspectives. Therefore, in order to ensure transparency and contribute to confirmability of the research findings in undertaking Phase II, the semi-structured interviews, the researcher maintained a reflexive diary. The researcher is a Rheumatology Specialist nurse who has experience and insights into the processes and delivery of giving information to patients about Methotrexate. The researcher was transparent with all interviewees prior to the interview taking place, and explained that she also had experience in the role. Her position as an "insider researcher" may well have contributed towards firstly, establishing a rapport with the participants, and secondly may have generated a shared understanding and empathy between the researcher and participant (Blythe, Wilkes et al. 2013). This connection may have empowered the participant to respond with a more frank and transparent discussion than would otherwise have occurred. The researcher was not an experienced interviewer, and as the interviews progressed, she became increasingly confident and familiar with the process. Whilst the researcher took care to ensure she conducted the interviews in a similar way with all participants and stayed close to the wording of the interview schedule, some interviews flowed more easily than others and more information was given. Reflexivity is a deep introspective self-exploration of one's own perspective (Patton 2014) allowing the researcher to develop an awareness of their own role and the impact that this may have on the research, it allows the researcher to acknowledge how their own experiences and beliefs may have affected the research processes and outcomes (Haynes 2012). The reflexive account of Phase II is discussed in the relevant section.

5.16 Data Analysis

The method used to interrogate the data was thematic analysis as the aim of the analysis was to explore the data, identifying specific themes and ideas to achieve an understanding of the nurses' experiences. But Sundler et al (2019) consider that when researching lived

experiences, the principles of phenomenology (see Chapter 3) guides that process, particularly the analysis. A phenomenological approach to the thematic analysis focussed on the human experience and is commonly used in social sciences (Guest, MacQueen et al. 2012). Table 5.5 describes the application of thematic analysis from the phenomenological perspective.

TABLE 5. 5 PHENOMENOLOGICAL THEMATIC ANALYSIS (GUEST, MACQUEEN ET AL. 2012)

Defining Features	Focuses on subjective human experiences Analysis is generally thematic Often used in humanist psychology and has been adapted to be used in humanities and social sciences
Epistemological Learning	Interpretive Subjective meaning is interpreted and extrapolated from the dialogue
Strengths	Good for smaller datasets can explore data more deeply and extrapolate beyond text Good for cognitively oriented studies
Limitations	Focuses only on the human experience May interpret beyond what is in the data

5.16.1 Method - Thematic Analysis

Analysis was carried out using a thematic analysis approach which systematically identifies, organises and offers insight into, patterns of themes across a dataset (Braun and Clarke 2012). Braun and Clarke describe six steps; familiarisation or data immersion which incorporates reading, re-reading and making notes; coding, where interesting features of the data are coded; searching for themes, the collated codes are gathered together into emerging themes; reviewing the themes, to ensure that the themes are relevant to the

coded extracts; definition of themes, which generates clear definitions; finally reporting, to select compelling extract examples to illustrate the themes and research question.

Firstly, the researcher must familiarise themselves with the data. This is the process where the researcher immerses themselves in the data, reading, re-reading the transcripts, making notes and cross referencing. The data is then organised into a series of "codes", or short statements which capture the meaning of that particular phrase. This stage of the process is important to the whole process as it underpins further analysis. In order to minimise researcher bias, note taking is important at this stage to demonstrate and justify a particular phrase selection or rejection through inter-rater comparisons to contribute to the reliability of the data. Secondly, themes are extracted from the data by combining and contrasting the codes. Thirdly, codes are further analysed to ensure all of the themes have been captured and to categorise the themes into sub-themes. The final step of thematic analysis is to build a theoretical model from the themes and sub-themes. This is the iterative stage of the process, where the themes and sub-themes are scrutinised multiple times by the researcher using cognitive and creative processes (Chapman, Hadfield et al. 2015). The following sections describe how these four steps were applied to the data resulting from the semi-structured interviews from Phase II of the study.

5.16.2 Data Immersion

The study researcher and a second researcher, a Consultant Rheumatologist who has 40 years' experience in Rheumatology and of managing patients on Methotrexate and was familiar with the study analysed the transcripts. Therefore, both researchers were familiar with the process of giving information to patients about Methotrexate. Both researchers worked independently of each other. They read and re-read each transcript whilst playing the interview recording at the same time. The aim of this was to familiarise themselves with the participant's voice and emphasis placed on words and sentences. Notes were made during this process to highlight areas where the participant may have weighted more importance to a statement through the emphasis of their voice. During the process of reading and re-reading the transcripts, the researchers both made notes on emerging themes and sub-themes. Each researcher then summarised every interview, incorporating the salient points and statements which arose during their immersion in the data. The

researchers then came together to discuss the themes and sub-themes and notes relating to the interview data to arrive at agreement and establish inter-rater reliability. There was a high degree of agreement between the two researchers and they had both recognised the main themes emerging from the data. There was more discussion around the sub-themes, and where agreement could not be reached, the data was re-visited by the researchers and discussed until mutual agreement was achieved. The recordings were then deleted once this step was complete.

5.16.3 Coding of the Data

Before commencing the process of coding Stuckey (2015) considers that it is important to develop a storyline which is directly linked to the research question ie "what is the data revealing which will help understand the research question". The summary of each interview which was generated through immersion in the data provided the storyline and therefore contributed to the decisions around concepts and themes which formed the analysis and guided the organisation of the data and coding method (Stuckey 2015). After completing the notes and summary of each interview, each transcript was re-read.

5.17 Findings

5.17.1 Demographic Details of the Participants

Demographic details, including the length of time participants had worked in Rheumatology and the duration of years participants had been involved in educating patients on Methotrexate, were collected (Table 5.6).

TABLE 5. 6 DEMOGRAPHICS AND EXPERIENCE OF THE PARTICIPANTS

Participants	Age	Years working in Rheumatology	Duration of interview	Previous Training
P1	65	25	45	Self-taught
P2	55	1	50	Watched colleagues
P3	48	6	60	Watched colleagues
P4	51	8	45	Mentored by senior colleague
P5	58	14	45	Mentored by senior colleague
P6	35	0.5	50	Mentored by senior colleague

The duration of time the Rheumatology Specialist nurses had been educating patients on Methotrexate varied from 0.5 years to 25 years. Three of the nurses educated patients immediately following the consultation in which they were recommended Methotrexate by a Rheumatologist. Whilst the remaining nurses conducted dedicated clinics with 30 minutes appointments to conduct the Methotrexate education. Three of the nurses had attended a degree level Rheumatology course and three nurses had received practical training in the workplace by their nurse colleagues.

5.17.2 Themes

Four main themes emerged from the data analysis:

1. Using standard written information to structure the content of the consultation
    a) Overloading patients with information
    b) Patients asking questions
    c) On-going support
2. Patients have different information needs

3. Time pressures
4. Training and evolution of practice

5.17.2.1 Theme One: Using standard written information to structure the content of the consultation

In response to the first question asked of the participants, can you describe a recent education session, there were varied responses. Some participants commented that they would commence the consultation by explaining what the purpose of the consultation was:

> "I always start off by having the patient reflecting….how they feel their everyday life has been affected by the arthritis and then try and put in context why we are starting Methotrexate….. (P5)
> "…when they go to see the doctors they don't know what they are expecting from us…so we have to discuss why they've come to see me" (P6)

Whilst other participants tended to start straight away by explaining what Methotrexate is:

> "I usually explain to them that this is a medication that does require blood monitoring" (P3)
> "I basically go through the booklet" (P2)
> "I would say, talking about DMARDs, particularly Methotrexate…we do follow a chart that we use" (P4)

When asked if the sessions varied, the participants responded that they had developed a dialogue using specific information to guide the consultation to ensure that the information that they felt was necessary to give to the patient was provided and thus ensuring that all of the information was given without deviation:

> "….the purple booklet (local patient information), the Methotrexate……and that's…I use that as my prompt……and using it to guide me through and keep me on track

and I seem to have my own little like speech and if I get thrown off my speech it sort of throws me a little bit" (P2)

"I usually use one of the ARUK leaflets about the…about Methotrexate…..so that we've got a plan to follow." (P4)

All of the participants used standard written information, which was in the form of the patient information booklet on Methotrexate. They described underlining or referring to important sections of the information booklets to ensure that the patients could read these sections again. The nurses clearly felt that certain sections of the information booklet were more important than others, and by highlighting this they were, in their own minds, ensuring that the patient had received this information:

"I normally put a little star by what I think are for them to take away important things to be read back…" (P4)

"I go through the purple booklet (local patient material) and use it to guide me through…it keeps me on track" (P1)

It was apparent that the literature given to the patients often acted as a check list for the nurse which acted as a prompt during the consultation. Using checklists confirms to the nurse that all information is given, ensuring that nothing is missed out and therefore satisfies her that the patient has received all of the information required to take Methotrexate safely:

"I use the headings (of the booklet) and then talk around that subject" (P5)

"I go through it you know …. so I know I've said everything I should and then on the back of our….checklist, …and it's got everything there like a tick so I go through that as well as I am going along." (P6)

5.17.2.1.1 Sub-theme: Overloading patients with information

A sub-theme emerged which disclosed that nurses were often aware of the amount of information they were giving to patients. Participants volunteered that patients were "bombarded" or "overloaded" with information and patients were described as being "dazed", "shocked" and "frightened". Rather than engage the patient more in the consultation, and explore their fears or feelings, the nurses encouraged the patients to take the information booklets and read them again at home in their own time.

> "..all the information I've just given you is written in this book, go home and read it again'…… because it is, 'it's all there for you to read again, if you…you know' because it is a lot to take in…….. you know in 10 minutes ….you can't possibly take it all in so…… 'you know it's there so go and read it"(P3)
>
> "I find that they've been totally bamboozled by the consultant they come out to me and they are a bit sort of dazed you know shocked at what they've been diagnosed with and then I feel as If sometimes I am telling them stuff but they are not actually taking it all on board" (P2)
>
> .."they get a little bit frightened…when you talk about it and some patients just don't want to take drugs". (P1)

5.17.2.1.2 Sub-theme: Patients asking questions

A second sub-theme emerged around giving patients the opportunity to ask questions. When the participants were asked if patients expressed their views during the sessions, it emerged that patients did not always ask questions during the consultation with the nurse:

> "I would say the majority don't, no they just sit and take it all in…"(P3)
>
> "I just didn't have enough time because I thought that she still had questions that she wanted to ask but didn't…" (P1)

But on some occasions the patients did ask questions but it seems that the nurses felt that it was more of an imposition rather than an opportunity to explore the patient agenda:

"..sometimes they want to know everything in that one sitting and you can't possibly do that.." (P4)

"I think the people who interrupt are the…the sort of the more, it sounds terrible….but the more intelligent people tend to interrupt and ask more questions" (P3)

"How often will I have to come to have for me to have my bloods done…that's a main one….I think that's it really.." (P6)

5.17.2.1.3 Sub-Theme: On-going support

A third sub-theme emerged on continuing support. All participants provided patients with the telephone helpline number to use for any follow up queries following the consultation:

"…but there is always a helpline and help at the other end of the phone"(P1)

"And we also offer them.....the Rheumatology advice line number and explain how and when they need to use that.."(P4)

And one centre offered patients the opportunity to make an appointment at an outreach clinic for follow-up support should they need it:

"… they've got the option of going to an afternoon appointment to one of the outreach clinics but it's still our staff that do them.."(P4)

The nurses also highlighted to patients that there were opportunities for patients to ask more questions and chat to a nurse when they returned to the monitoring and drug escalation clinics:

"and it's the sessions that they come for monitoring afterwards that they start to get a bit more involved and ask questions there."(P2)

"But quite often they do come back to the DMARD escalation clinic"(P3)

"When you come for your first monitoring if you remember anything just write it down and who ever does the monitoring with you, you know you can ask them." (P6)

5.17.2.2 Theme Two: Patients have different information needs

The nurses recognised that there were important variations between patients with respect to their need for information as perceived by participants and described occasions where they would give more information to some patients, but others, they felt, were not engaged in receiving information about the treatment they were about to start:

> "…go into it a little bit deeper than …than others, others just want treatment and no matter what it is as long as they can get rid of their pain…" (P1)
>
> "…I think particularly if they are new patients and they've never been on anything before they have a lot more concerns.." (P5)

The participants described the challenges encountered when talking to patients who are about to commence multiple drug therapy. Multiple drug therapies have been prescribed for patients with early Rheumatoid Arthritis for a number of years (Saunders, Capell et al. 2008, Moreland, O'Dell et al. 2012). These patients often find themselves in a situation where they have just had a diagnosis of a long-term incurable disease, for which they have to take up to 3 toxic drugs. For these patients, they need information about Rheumatoid Arthritis, and the life-long implications of this and they also need to understand how to take each drug safely. The implication of this for the patient can be overwhelming:

> "Because triple therapy has come out that's a problem we find…….I don't like to bombard people with too much so doctors like us really to start the triple therapy but you might start Methotrexate and hydroxyzine then come back to the sulfasalazine it's bombarding people and going out and saying 'Whatever has that nurse said to me.." (P5)
>
> "I do find it hard on the ones who have maybe got...two sets of drugs….you bombard them with two lots.." (P2)

The nurses reported that they would adjust the amount of information given to patients if they already had some knowledge of their disease and treatment. They therefore did not necessarily reinforce the information they already had:

> "..I talked to… about Methotrexate they'd already been on a few DMARDS before so it was loads easier because they already know the ins and outs of the disease and their condition." (P6)
>
> "sometimes you can fly through….because they seem to have grasped everything you take in.." (P2)

5.17.2.3 Theme Three: Time pressure

Time is often a challenge that nurses face on a daily basis (Chan, Jones et al. 2013) and whilst nurses value the time they spend with patients they often feel that they find it difficult to find time to talk to patients because of the pressures of the other tasks they have to undertake (Chan, Jones et al. 2013). Pressures of time were also apparent for all participants in this study and those pressures appeared to influence how they conducted the consultation:

> "….. because we are under pressure you know if you've got a queue of 10, 15 people waiting you know" (P3)
>
> "I mean for example if you got a patient that's newly diagnosed and Methotrexate is the first DMARD that they've ever come across that they are going to go on to it I do think you have….you need more time really with that patient.." (P4)

One participant also revealed that the process of giving information to patients required different amount of time depending on the patient, but also acknowledged that they were aware of the time pressure and that other patients may be waiting outside:

> "My honest answer is I take as much time as it takes.....if the patient I feel needs that extra time to go over it and over it they get it, simple as because if there is anybody waiting outside, tough they wait but I know that we are under that pressure 'Come on you know there's a queue" (P2)

There was general agreement amongst the nurses that most patients need information spread over several appointments which seems to indicate that they were aware that the amount of information given at one session should be spread over several appointments:

> "..so it becomes an on education all the time follow on all the time, or it should be it should be." (P1)
>
> "Don't worry, we will go week to week and we will get there" (P5)

One participant also acknowledged that the patients themselves understood the time pressure and believed that the nurse's time was precious. The nurse here also appeared to have a perception of the time pressure on herself, which inhibited her from probing further into the needs of the patient:

> "I just didn't have enough time because I thought that she still had questions that she wanted to ask but didn't" (P1)

One participant had an awareness that sometimes patients needed time to decide to take the drug and did not put the patient under any pressure to start taking the drug. However, rather than addressing the patient's concerns at that meeting, the patient was left to make the decision for themselves:

> "..so we leave it open that they can contact us to start it before the review.." (P5)

The nurses also added that some patients simply will not take the drugs at all even though reassurance on the safety of Methotrexate is given:

> "some patients just don't want to take drugs…they just don't want them…they just think well I will just master on with some herbal remedy….but we try to spend time educating them and telling them the safe side….it is a good drug for Rheumatoid Arthritis" (P1)

5.17.2.4 Theme Four: Training and evolution of practice

Most participants agreed that when they first started giving patients information about Methotrexate, it was an experience that they sometimes found frightening and were under confident. One nurse remained underconfident despite having carried out the role on a number of occasions:

> "..at the beginning it might frightened you ……..(P5)
> "Yes. I mean a lot of the time I'll check with somebody else something that I know I am doing the right thing but it's just that added reassurance…"(P6)
> "..and although I've had lots and lots of patients….and done lots and lots of monitoring clinics with Methotrexate and the other DMARDs, I am still not 100% satisfied that I know enough about that drug for to educate a patient." (P1)

Training to carry out the role on giving information about Methotrexate varied between the participants. Some nurses revealed that they had not received any training at all:

> "….my training was when we were first started using Methotrexate……..after using things like.….drugs like Gold and penicillin mainly and sulfasalazine was none, I didn't have any training what so ever."(P1)

Other participants described their training as consisting of observing the doctor or nurse:

> "..I even tried to get sessions where I could go in with the doctor and sort of listen to what they were saying" (P2)
> "It got more clearer when I got on the outpatients because...I didn't start doing the counselling sessions straight off …I sat in with (Name of person) a few times.." (P6)

None of the nurses had been given any formal training about Methotrexate and how to deliver information to patients.

All participants described that their practice had evolved with experience and time, picking up information from their colleagues and absorbing how they carried out the role:

"….but then, I think as time goes on you do, you learn more because you know when you are sitting and monitoring you can…..you can hear what other people are telling the patients and so you pick up little snippets" (P3)

"..and to me it's like driving, you can have your lessons, you take your test but you don't really learn to drive until you are behind that wheel on your own do you?" (P4)

However, it was clear that all of the nurses agreed that there was a need to keep up to date with practice as it evolved, but again there was no formal training around this and there was no expectation from the nurses that this would be provided. There appeared to be an acceptance, that they would just pick this up as they went along:

"..and even to this day I would still say I need to be educated in it further." (P1)

"It's like the shingles vaccine there's been a lot of talk around that." (P5)

One participant even described learning about side effects from patients who expressed their experiences of Methotrexate to her:

"..but you still don't learn as much, I don't think, as you do from patients coming in and saying 'Well I've got this side effect, I've got that side effect" (P3)

When the nurses were asked if they thought formal training would have helped them carry out this role, all of the participants agreed and they offered some suggestions around what form this training could take:

"…. like maybe in-house training on the computer that I could maybe read and get a background on…." (P2)

"I think it's good to have formal session so that the nurse knows exactly what she is supposed to say and then as a backup I think the….that role play thing would be good ..." (P4)

5.18 Discussion

5.18.1 Summary of Results of Phase II

This second phase of the thesis explored how the nurses felt about conducting this role, what they observe from their patients and how they felt about their training. The semi-structured interviews captured the experiences and perceptions of six nurses who give information to patients about Methotrexate. Phase II revealed that the nurses' consultations focussed mainly on their own agenda of giving the information about Methotrexate to the patients. They all used an information booklet about Methotrexate to guide their consultations and also considered checklists useful to guide and help them during the process. The nurses recognised that they were giving a lot of information to patients; the patients often appearing "bamboozled" or "shocked", but the challenges of time pressures resulted in few opportunities for patients to ask questions and nurses described feeling "off track" if they did. The nurses also recognised that different patients have individual learning needs, but questions were not encouraged as the perception of time constraints and the need to give the information dominated the consultation. All of the nurses agreed that they had learned of the job from their colleagues, but they would have liked a structured formal training which would have had a positive impact on their skills, confidence and knowledge.

The results of Phase I of the study, the national survey, highlighted that there is no gold standard formal training for nurses in the UK to carry out the role of giving information about Methotrexate in order for patients to take this drug safely and as prescribed. It also revealed that nurses can take between six months to a year to feel confident about carrying out this role. The survey also showed that nurses learn on the job and eventually become reasonably knowledge about the salient information around Methotrexate safety. However, it also disclosed that nurses basically learn on the job from each other, therefore bad habits as well as good habits could be passed on within the same service.

5.18.2 Discussion of Themes

5.18.2.1 Theme One: Using standard written information to structure the content of the consultation

The majority of the consultation focused on the nurse's agenda of imparting information about Methotrexate to patients going straight into that agenda without necessarily addressing whether the patient had an agenda. Nurses used an information booklet about Methotrexate as their guide (see Appendix 2). This information booklet was primarily produced for use by patients; therefore, it is designed in a language that delivers information at a literacy level which will ensure that most patients reading it will absorb a basic understanding of Methotrexate. The ability to understand health-related information has a measurable effect on treatment outcomes (Fields, Freiberg et al. 2008). A study by Schillinger et al (Schillinger, Piette et al. 2003) showed that diabetic patients who had higher health-literacy levels had better control of their diabetes when their physicians adapted their language to the literacy of their patients. Whilst the Methotrexate booklet is an appropriate information source for patients, the use of this booklet as a primary information source for nurses could be questioned. However, the national survey conducted in Phase I of this study, clearly revealed that there are few information sources for nurses around Methotrexate and how to give this information in their consultations. It is also clear from the literature review, that consultation techniques are not part of standard training for nurses (Nursing and Council 2010) thus it is not surprising that nurses structure their consultation with written sources. The nurses also revealed that using checklists was useful and helped them to guide their consultation with the patient, ensuring that no information was missed. However, whilst it could be said that checklists encourage safer information giving, they could also encourage "mindless" checking, which promote automaticity and discourage conceptual thinking (Catchpole and Russ 2015). Thus, using a checklist during a consultation with a patient when giving information, could generate a dialogue which solely relies on the checklist without accounting for the patient and their personal needs. It could lead to giving information "rote fashion" without individualising and tailoring the consultation from the patient perspective and addressing the patient agenda. It was clear that the nurses interviewed understood the purpose of their consultation, but their practice of using a checklist approach to inform the content of the consultation reduced the

opportunity for the patient to ask questions and issues that are important to patients and which might impact on concordance are unlikely to be discussed. (Macdonald, Stubbe et al. 2013) video recorded 35 consultations between ten nurses and 18 patients who had Type 2 Diabetes Mellitus. The initial consultation involved the extensive use of checklists and was driven by the nurses' clinical agenda rather than what the patient already knew or wanted to know. Whilst checklists can be helpful for nurses by ensuring that important information has been delivered to the patient, they might prevent the patient asking the questions that will influence their decision whether to commence the medication being advocated.

The nurses also recognised that they were giving a lot of information to the patients, who they described as appearing bamboozled, overloaded, dazed, shocked and frightened. Patients in this state would probably find it very difficult to absorb any new information regarding their medication, which appears to be reflected in participant 3's account of patients sitting and "taking it all in" without asking any questions. Nevertheless, the overriding objective of the nurse was to give this information to the patients. Again, this could reflect the lack of training nurses have to carry out this role and how to conduct effective consultations. Rhodes et al (2006) examined the interaction between nurses and patients with a long-term chronic condition, diabetes type 2. They video-recorded 25 consultations between nurses and patients with diabetes type 2 and revealed that by using checklists the nurses streamlined their interaction with the patients. They also referred to "industrialisation" which is characterised by treating large numbers. If this case, "familiarity" may breed "complacency" and some practitioners have come to regard it as "a grind" where patients become commodities to be processed rather than individuals. This restricts the patients' opportunities to become individuals and the nurses reduce the potential for patients to disrupt their rapid and streamlined process (Richardson and Kerr 2002). This may also account for the few opportunities provided by the nurses during their interaction for questions from patients, which is supported by the conclusions of Rhodes et al (2006). They determined that their findings from the analysis of the video-recorded consultations between the nurse and patient revealed that there was a failure to conform to any of the dimensions of patient centred care.

All of the nurses ensured that the patients had access to a helpline should they have any further questions or concerns. One service offered an outreach clinic, where patients could

make an appointment to see a nurse and have further discussions. However, there appeared to be little discussion around how to use this service, it appeared that the signposting to the helpline and outreach clinic was a way of finalising the consultation.

5.18.2.2 Theme Two: Patients have different information needs

The nurse participants recognised that patients had different information needs which could be challenging to respond to within a time bound consultation. Their lack of standard training in consultation technique does not arm the nurses with the knowledge and skills required to manage this situation. Participants reported discussing the purpose, administration, contra-indications and side effects of Methotrexate guided by the information booklet, but patients then have to make sense of the information given from their own perspective. The meanings that patients develop will vary, influenced by factors such as their beliefs, past experience, education, culture and intelligence (Goodacre and Goodacre 2004). It is therefore necessary to check the patient's understanding at frequent intervals. The nurses did not report using this consultation technique when addressing the patients. Thus, it appears that a patient-centred approach may not have been adopted in their encounter with the patient. Putting the patient at the centre of their care has been shown to increase patient engagement, satisfaction and compliance with treatment (Mirzaei, Aspin et al. 2013). Whilst many healthcare professionals accept the concept that shared decision-making and putting the patient at the centre of care, can be empowering to the patient and have an impact on their disease, it is still not being utilized widely and it is difficult to determine whether it is making an impact (Légaré, Adekpedjou et al. 2018, Mathijssen, Vriezekolk et al. 2020). The findings of the semi-structured interviews seem to support this perspective as the nurses did not appear to individualize the patient and develop the interaction with a shared decision-making approach.

5.18.2.3 Theme Three: Time pressures

The nurses' perceptions of the limitation of time for their consultations appeared to have an impact on their willingness to encourage questions from the patients. Participant 3 used

the word “interrupt” which could indicate that this nurse was under time pressure to deliver the Methotrexate counselling to the patient and therefore did not engage in encouraging questions. Bowers et al (2001) interviewed 18 nurses who worked in a long term care environment. They found that the nurses had too little time to perform all of the tasks required of them and this often led to developing strategies to reduce the time allowed to complete certain duties. Effectively, the nurses sometimes would not do those tasks that they regarded as “should do” and concentrated on those that they “must do”.

It is reported that there is a global shortage of nurses as a result of lower recruitment and a higher turnover rate of qualified nurses (Nantsupawat, Kunaviktikul et al. 2017, Senek, Robertson et al. 2020). Senek et al (2020) conducted a survey of nurses in the UK and they found that nurses felt demoralised because of a perceived lack of support, low staffing issues and poor management. Low staffing issues resulted in higher than manageable patient to staffing ratios which had a detrimental impact on both the nurse and the patient. Thus, the pressures of not having enough perceived time to conduct the role of giving information about Methotrexate to patients could result in “rote fashion” consultations. Some participants described having a “speech” and “keeping on track” which could imply that their agenda was the focus of the consultation resulting in a lack of opportunities for patients to ask questions or discuss concerns.

5.18.2.4 Theme Four: Training and evolution of practice

The emergent role of the Rheumatology nurse was described in Chapter 2 Section 2.4, and it revealed that nurses were increasingly taking on more tasks such as joint examination, disease management planning and drug prescribing (Hill, Thorpe et al. 2003, Goh, Samanta et al. 2006). A survey undertaken by the Royal College of Nursing (Royal College of Nursing 2009) revealed that a small number of nurses had undertaken drug prescribing courses, cytotoxic drug courses and a small number of Rheumatology courses. The implication of this was that most Rheumatology Specialist nurses had no formal training to conduct their developing roles. This lack of training was also apparent within the participants of Phase II of this study; the analysis of the transcripts revealed that none of the nurses interviewed had undertaken any formal training to carry out their role. They had generally learned on

the job, absorbing the techniques of other colleagues and even expanding their repertoire of knowledge from the experiences of patients around side effects. But, it is difficult to understand how far colleagues from the same service, had influenced their consultation style. Whether, good or bad habits had been passed on, or how far the individual nurse had sought more information herself to become more informed. Nonetheless, all nurses agreed that formal training would have made a positive impact on their skills, knowledge and confidence, which supports the findings of Phase I of the study, the national survey.

5.19 Limitations of the Data

5.19.1 Recruitment Sampling

As discussed in section 5.8 of this chapter, six nurses were recruited to Phase II, three each from two different NHS Trusts. The Trusts differed in that one Trust offered a structured University course on Rheumatology Nursing and nurses who gave information about Methotrexate had dedicated appointments for the patients in which to carry out their consultations. The other Trust offered no training, apart from what would be gleaned on the job, and the nurses fitted in the task of giving information about Methotrexate to patients whilst they were conducting other duties in the outpatient department. The rationale behind recruitment from these two different services was simply because it was extremely difficult to engage enough nurses in one Trust to agree to be interviewed. There was a great deal of reluctance on their part despite assurances that all interviews would be anonymised and confidential. Whilst it could be considered that the learning opportunities and the dedicated time for consultations could have had an impact on the way information about Methotrexate was given, in fact, the same themes emerged from the interviews with the nurses from each Trust; for example, all nurses used the Methotrexate information booklet as a check list and all of the nurses had their own agenda of ensuring that all of the information was given.

5.19.2 Data Saturation

Samples for qualitative research are generally smaller than those required for quantitative investigation (Mason 2010), because as the study progresses, it does not necessarily mean that more information is obtained. Mason (2010) articulates that the occurrence of one piece of data or code is all that is required for it to become part of the data analysis framework, further stating that frequency is rarely important in qualitative inquiry because one piece of data can be as important as many in the understanding of a research topic. Furthermore, analysing qualitative data can be very labour intensive and therefore large sample sizes for some projects can be impractical (Green and Thorogood 2018). Green and Thorogood further believe that whilst data saturation is a credible concept it has weaknesses in that some researchers may be limited by time through the conditions of their grants and they may also have to identify the number of participants to be interviewed for a grant committee or an ethics committee before they study begins. Mason (2010) reviewed 560 PhD studies in which interviews were conducted as part of the projects, the number of interview participants ranged from one to 95 and there was no real pattern of how the researchers arrived at their sample sizes. Guest et al (2006) recognised that there were no real guidelines around how to estimate sample sizes for purposive sampling interviews. They investigated data saturation and variability by conducting semi-structured interviews with women from two African countries; 30 participants were from Nigeria and 30 were from Ghana. An interview guide was used and all interviews were audio-recorded then transcribed verbatim. Thematic analysis of the transcripts was carried out and codes were defined. Their aim was to determine whether six interviews rendered as much useful information as 12 or 18 for example. After analysis of all 60 interviews, 36 codes were applied and they concluded that of these 34 (94%) had been identified within the first six interviews and 35 (97%) within the first 12 interviews. Therefore, whilst the results may not necessarily be considered generalisable, nor be truly representative of the respondents who completed the Phase I national questionnaire, six to 12 interviews should yield enough information to understand common perceptions and experiences amongst a group of relatively similar individuals. Thus, whilst the findings which emerged from the semi-structured interviews described in this thesis, may not necessarily be considered generalisable, they yielded enough information to be able to contribute to the body of

existing knowledge in this particular area of investigation. They provided further insights into how nurses conduct their interactions with patients when giving information about Methotrexate.

5.20 Areas for Further Investigation

As drug counseling/education is regarded as a key role of Specialist Rheumatology Specialist nurses (Royal College of Nursing 2009), a training programme could be developed which would include effective consultation skills to maximize the time-bound consultation and increase confidence to enable a two way communication process where a guide is no longer required to structure the consultation and the encounter can be patient-led.

Further investigation of how nurses conduct their consultations with patients in order to understand the underpinning evidence-based practice they employ is required. It is unclear how far the nurses' practice shared decision-making and which consultation model forms the structure of their practice. Direct observation through video recording will allow the researcher to observe the process in detail. Thus, Phase III of this study involved video-recording ten nurse patient consultations from one Rheumatology service, the aims of which were to further explore the consultation skills of the nurses and how shared decision-making was incorporated into their practice. Further, by video-recording nurses from one Rheumatology service who have observed each other, it allowed the researcher to investigate how far the nurses were influenced by each other in a "copy-cat" fashion, or whether they developed their skills into their own individual styles.

Chapter 6: Phase III – An exploration of video-recorded consultations between Rheumatology Specialist nurses and patients

6.1 Summary of Phase II

Phase II of this study explored the experiences and perceptions of six nurses who gave information to patients about Methotrexate through audio-recording semi-structured interviews. This revealed that the nurses' agendas during this process dominated the consultation resulting in a lot of information being given to patients. Patients were described as appearing "bamboozled", "dazed" and "shocked", but the nurses perceived that the challenges of time pressure resulted in little opportunity for patients to ask questions, or if they did, the nurses sometimes went "off-track" with the flow of their consultations. The nurses recognised that different patients had different learning needs, but it was not apparent that the nurses were tailoring their consultations to meet these different needs. All the nurses had learned their skills on the job, by watching peers and Rheumatologists in clinics, but they all agreed that structured formal training would have been more appropriate and would have had a positive impact on their knowledge, confidence and skills.

The Nursing and Midwifery Council standards for pre-registration nursing education (Nursing and Council 2010, Nursing and Midwifery Council 2018) require student nurses to develop a range of communication skills in order to demonstrate those skills:

"underpinning communication skills for assessing, planning, providing and managing best practice, evidence-based nursing care" (Nursing and Midwifery Council 2018:20).

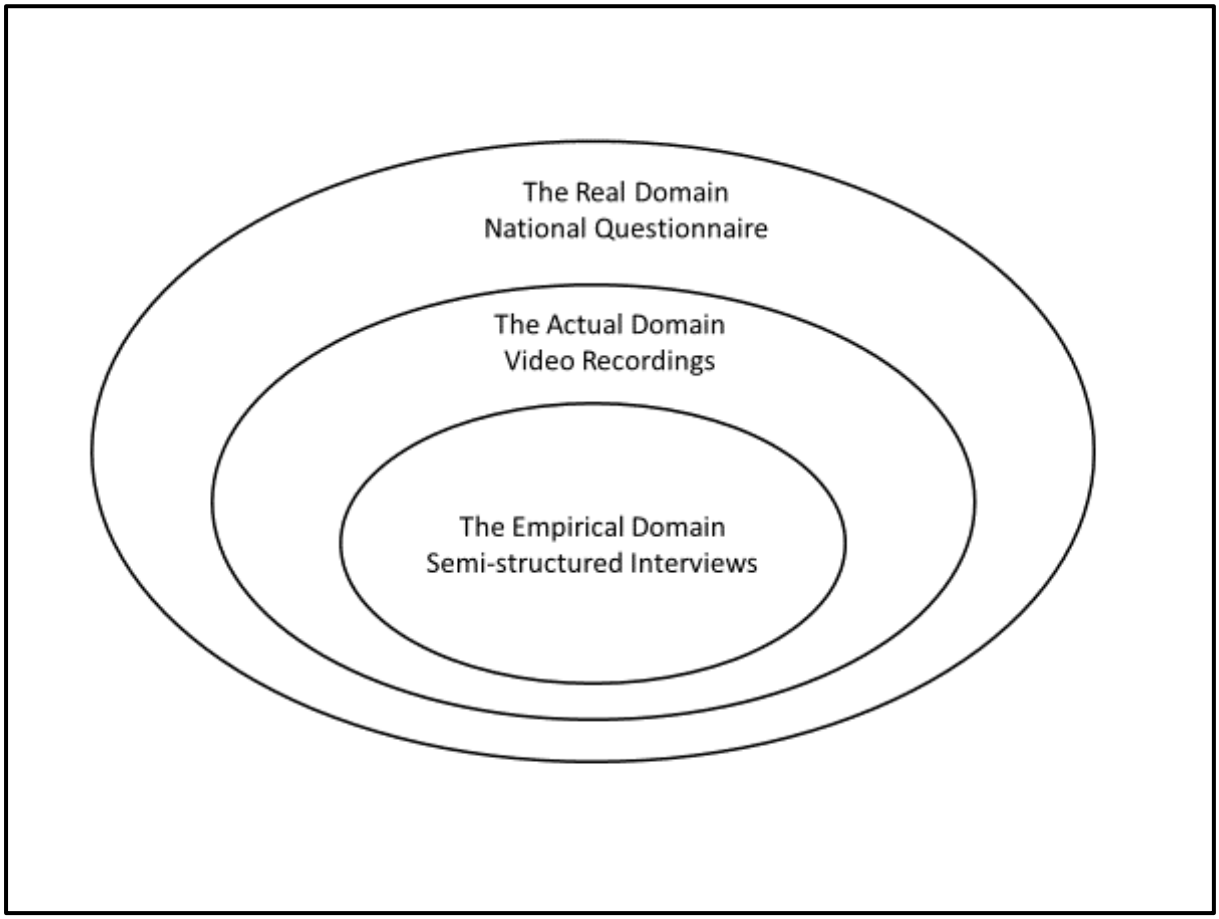
This appears to suggest that there is an expectation that the student nurse will understand how to actively listen, recognise and respond to verbal and non-verbal cues, make appropriate use on open and closed questioning and check understanding and use clarification techniques. However, the emphasis appears to be on the development of the nurse's knowledge rather than developing the underpinning consultation and teaching skills.

These latter skills are often emphasised more in postgraduate courses. This final third phase of the study aims to investigate more closely how nurses use open and closed questions during their consultations and whether they recognise and respond to verbal and non-verbal cues from the patients.

6.2 Phase III Introduction

This phase of the study, investigating the actual domain from the philosophical critical realism perspective, was undertaken by video-recording ten nurse/patient consultations (Figure 6.1).

FIGURE 6. 1 PHASE III VIDEO-RECORDED CONSULTATIONS WITHIN THE CRITICAL REALISM PHILOSOPHICAL FRAMEWORK



Prior to commencing Methotrexate, patients receive information in a consultation with a nurse. The purpose of this is to give the patient sufficient information about the drug's likely effects and possible side effects to allow them to take it safely and effectively. The patient's wish to start the drug is confirmed and the arrangements for monitoring and supply are discussed. Results from the previous two phases of this study confirmed that further exploration of the consultation between nurses and patients when giving information about Methotrexate was required. As reported in Phase I, the national survey, nurses had variable and limited training in order to undertake this process. Confidence in this role took time to develop and was linked to gaining experience. The results from the semi-structured interviews (Chapter 5) showed that the nurses focused mainly on giving information which led to little opportunity for interaction and questions from the patient. The objective of this phase of the study was therefore to video the interaction between the Rheumatology Specialist nurses and patients during the information giving process about Methotrexate for comparison with a consultation model and for thematic analysis in order to further explore and understand the nurse and patient experience of the interaction.

6.3 Phase III Aims and Objectives

6.3.1 Phase III Aims

To investigate how nurses, deliver information about Methotrexate to patients, and how they ensure that patients have received and understood that information during the consultation process.

6.3.2 Phase III Objectives

1. Video record ten nurse/patient consultations.
2. Analyse the video recordings using the Medical Interactive Process and the Calgary Cambridge Model.
3. To understand the processes nurses, use in their interaction with the patients when giving information about Methotrexate.
4. To understand the processes nurses, use to ensure that patients have understood the information given.

6.4 Methods

6.4.1 Video-Recording

The aim of this phase was to explore the non-verbal aspects of the interaction as well as the verbal aspects, and therefore video-recording was the most appropriate method of data collection.

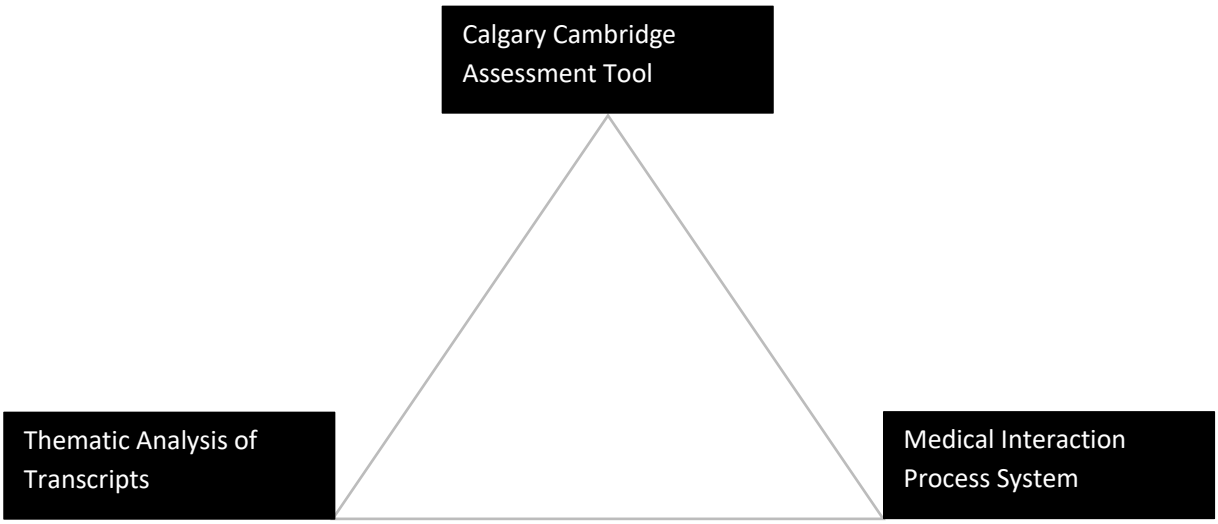
Video-recording has developed into a powerful tool for research in the social sciences (Janík, Seidel et al. 2009). It allows the study of complex processes, increases inter-rater reliability, and coding from different perspectives can be undertaken (Hiebert, Gallimore et al. 1999). The use of a video camera could also be viewed as less intrusive than a physical presence by the researcher. The video-recording allows the whole interaction between nurse and patient to be captured in order to investigate effectiveness of the consultation (Heath, Luff et al. 2007). One option would have been to sit directly in the clinic and observe. This would only have allowed one "take" of the consultation which would therefore have been limited to an impression of how different aspects of the consultation were performed. This may have been suitable for scoring the consultation against pre-defined content as to how well the different items were performed, but it would not allow any more detailed analysis and the presence of the observer may have distorted the consultation. Audio recording of the consultation would have allowed the more detailed qualitative analysis but only of the verbal content of the consultation. The presence of the camera in the consulting room would be less intrusive than an observer and therefore less likely to distort the consultation (Heath, Luff et al. 2007). From previous experience the subjects very quickly appeared to forget that the camera was there. The analysis of the video-recordings was achieved through; scoring against the Calgary Cambridge model, scoring using the Medical Interaction Process System and thematic analysis of the transcripts. The adoption of multiple analysis methods can add depth to the findings of a study and is therefore given further consideration in the following section.

6.4.2 Triangulation

The term "triangulation" originates in the field of navigation where a location can be determined from two known points (Heale and Forbes 2013) but in research it is the use of

more than one approach to addressing a research question. The objective is to add rigor, breadth complexity, richness and depth to the enquiry, (Denzin 2012) and is considered an important method regarding data analysis for qualitative studies to ensure reliability and validity of the results (Fusch, Fusch et al. 2018). Triangulation is generally associated with research methods and designs, but it also includes the adoption of multiple theories, data sources, methods or investigators within the phenomenon under examination (Williamson 2005, Lauri 2011). A discussion of mixed methods research has already been carried out in this thesis (see Chapter 3 section 3.5). The review discussed criticisms concerning mixing qualitative and quantitative methods in a research project and whether these methods would be compatible (Creswell 2011). However some researchers consider that not all research favours a single method approach and the strengths and limitations of the qualitative and quantitative paradigms add to the richness of the resulting conclusions and may capture a different perspective which may otherwise have been overlooked (Morse 2009, Maxwell and Mittapalli 2010). The discussion of mixed methods in Chapter three concluded that the overall three phase study presented in this thesis can be regarded as truly mixed methods and triangulation of the methods of analysis for Phase III was adopted to add rigor and strength to the findings (Figure 6.2).

FIGURE 6. 2 TRIANGULATION OF ANALYSIS METHODS FOR PHASE III



6.4.3 Calgary Cambridge Assessment Tool

A number of consultation models have been developed, which were described in Chapter 3, but they were designed for use in the medical domain. Consultation models create the framework of the consultation and most are patient-centric (Perry 2011). Perry recognises that nurses will adapt and formulate their own consultation structure but seven key elements should be; establishing and maintaining a good rapport, structuring the consultation, obtaining and gathering relevant information, prioritising, clinical reasoning and judgement, information giving and management planning involving the patient. The Calgary Cambridge Model is used in many medical schools to teach students how to carry out a consultation (Kurtz, Draper et al. 2017) and is widely practised amongst General Practitioners (GPS) (Burt, Abel et al. 2014). This model emphasizes the need to provide information in manageable chunks and to use the patient's response to guide the consultation (Kurtz, Silverman et al. 2003). Whilst this model was developed for the medical profession, it has been adapted to apply it in the nursing context (Munson and Willcox 2007). The Calgary Cambridge consultation model (Kurtz and Silverman 1996) has five stages and two themes which run through the consultation (Denness 2013);

- initiating the session to establish the reason for the consultation and set an agenda
- gathering information about current knowledge, ideas concerns and expectations where open and closed questions would be used, also picking up on cues
- physical examination
- building the relationship with rapport and empathy and legitimising the patient view,
- explanation and planning which includes, chunking of information and checking for understanding, using written information
- closing the session, which would include summarising and ensuring that there is an agreed and clear plan
- Providing a structure with a flow and clarity

The Calgary Cambridge consultation model is a proven standard for consultations involving the transfer of knowledge and consultations by nurses using this model and nurse/patient communication skills can be improved by applying this consultation model. In China Yian et

al (2012) commented that training of nurses using this model resulted in improved observed communication and interview skills. Donnelly et al (2016) recognise that applying the Calgary Cambridge consultation model can result in more meaningful, empathetic communication between the nurse and patient in the palliative care setting. McLeish and Snowdon (2017) applied the Calgary Cambridge consultation model to illustrate that prescribing decisions can be enhanced and provide direction to the consultation. Whilst nurses who talk to patients about Methotrexate do not necessarily need to apply the full model, elements of it could enhance their consultation skills for this particular role (Munson and Willcox 2007). Patients also have different preferences for communication (Macdonald, Stubbe et al. 2013) and, to optimize concordance, the nurse needs to be able to identify the patient's information preference and meet it. It meets the seven criteria described by Perry (2011) and has been adapted to be applied in the nursing context and was therefore selected as an appropriate model with which to assess the consultation techniques used by nurses in the video-recordings for this phase of the study.

The videos were viewed in VLC Media Player which is a free playback application (Hughey and Maaks 2020) and allowed the researcher to stop and start each video-recording in order to code the data. The videos were reviewed multiple times in order to ensure that every domain of the interview had been meticulously analysed. Each recording took approximately five hours to code. One video was scored separately by a second researcher, who was part of the supervisory team and was a Consultant Rheumatologist, for inter-coder reliability to achieve agreement. He was therefore familiar with the study and knowledgeable around the information which patients require in order to take Methotrexate safely and as prescribed. The aim of this was to ensure that the coding produced by the researcher could be reproduceable by other coders. Inter-coder reliability is carried out by two or more equally proficient coders for the same data (Popping 2010) and inter-coder agreement is the discussion that the two or more coders have with regards to any coding discrepancies they may have had (Campbell, Quincy et al. 2013). The two researchers discussed and agreed the coding assessment tool prior to conducting the assessments.

As discussed in Chapter 2 (section 2.7), a number of assessment tools are available to evaluate consultations including the Royal College of General Practitioners Consultation

Assessment Tool (COT) (2017) containing 13 items with which to score the consultation on a zero to three scoring scale. However, as previously discussed, not all of the domains were applicable and there was some overlap with the Calgary Cambridge consultation model. Consequently, the scoring system was aligned with the domains of the Calgary Cambridge consultation model (Table 6.1), removing the domain around physical examination as this would not have been carried out during the consultation under investigation, but the zero to three scoring scale of the COT was retained (Table 6.2).

TABLE 6. 1 SCORING SYSTEM BASED ON THE CALGARY CAMBRIDGE CONSULTATION MODEL DOMAINS

Domains
Initiating the Consultation
Setting the Agenda
Information/Knowledge
Ideas/Concerns/Expectations
Explanation and Content
Chunking - Checking
Written Information
Closing Summary

TABLE 6. 2 THE 4-ITEM SCORING SCALE BASE ON THE COT

SCORE	**OBSERVATION**
0	No Evidence
1	Needs Development
2	Competent
3	Excellent

6.4.4 The Medical Interaction Process System Scoring Tool

Whilst the Calgary Cambridge model provide an overview on how healthcare professionals conduct their consultations ensuring that the patient is central to their care and understands and shares the decisions around their disease management, it did not factor in non-verbal communication. Communication is a highly complex process involving far more than the spoken word (Kourkouta and Papathanasiou 2014). Kourkouta and Papathanasiou believe that not only understanding the patient is required but also the nurse must convey messages which the patient understands and are acceptable. They also believe that nurses require training in order to carry out this communication effectively. Characteristics of communication, which should be observed in order to achieve a meaningful interaction are described by Ford and colleagues (2000) (Table 6.3).

TABLE 6. 3 CRITERIA FOR AN INTERACTIVE PROCESS SYSTEM (BASED ON FORD ET AL 2000)

CRITERIA	CHARACTERISTICS
Information Transfer	Content – containing definitive and connotative information usually transmitted linguistically Relationship – affective information which can be transferred by facial gesture, tone of voice, grammar etc
Context	Refers to the current situation and adds to the relationship level
Observation Method	Video recordings capture all of the verbal and non-verbal behaviour
Sequencing	Observing the relationship between each statement and the verbal utterances between the participants
Coding System	Logical with clear concise understandable category definitions

Non-verbal "body language" by some estimates, accounts for more than half of communication (Mehrabian 1981). In order to explore this further a more detailed analysis was undertaken. One of the most detailed analyses described is the Medical Interaction Process System (MIPS) which codes every utterance and every movement by both the educator and the patient (Ford, Hall et al. 2000). This tool was based on the work of Roter

(1991), who developed the Roter Interaction Analysis System (RIAS) which is an instrument for observing and coding verbal interaction. One of the limitations of the RIAS was that it did not consider the non-verbal behaviour and patient cues which adds a further dimension to the consultation. Therefore, Ford et al refined the RIAS so that these interactions could also be coded and analysed.

The RIAS was considered at a method for data analysis for the study presented in this thesis as it has been used extensively in healthcare research (Pires and Cavaco 2014). Pires and Cavaco conducted a systematic review of studies using the RIAS and from the 34 articles which were selected for their review, only four involved nurses. Vinall-Collier et al (2016) video-recorded 18 healthcare professionals nine of which were Rheumatology nurse specialists. The aim of that study was to compare the styles of interactions with patients between nurses and physicians. They coded the videos using the RIAS which was categorised into four domains; data gathering, patient education and counsels, activate and partnership and building a relationship. However, as previously discussed, the RIAS does not encompass the verbal and non-verbal domains which are part of the MIPS analysis. Thus, in order to explore both the verbal and non-verbal domains, and add greater depth to the findings of this study, the MIPS was adopted. Further, a review of the literature did not reveal the use of the MIPS to code and analyse the interaction between nurse and patient in any studies, it was therefore of interest to adopt this coding method in a unique and novel setting. The basic unit of the MIPS is the utterance where each one is coded separately and the content of that utterance is coded which includes both verbal and non-verbal interactions. This was a novel approach in the exploration of consultations between nurse and patient in Rheumatology. Further, the quantification of all verbal and non-verbal utterances and actions permitted a quantitative and potentially more objective analysis of the interaction.

In order to carry out the analysis of each video-recorded consultation and observe the verbal and non-verbal interactions between the nurse and patient during the process of giving information about Methotrexate, the videos were viewed multiple times. The first ten-minute segment of each of the consultations was analysed. The decision to analyse the first ten-minute section was reached because it allowed the researcher to explore the initial greeting made by the nurse to the patient, how she determined the patient agenda and

how she set the scene. Further, it would also reveal how the nurse gave information to patients, and how she engaged with shared decision-making, putting the patient at the centre of the consultation. Focussing the analysis to a ten-minute segment has been used in other studies. Caris-Verhallen et al (1999) who observed the non-verbal behaviour of nurses in care homes and own home settings. They followed Henbest and Fehrsen (1992) who noted that scoring a ten-minute segment of a communication was as reliable as scoring the whole encounter. Further Kaner et al (2007), who conducted a video-based study comparing standard paper based guidelines with two forms of computer based decision aids to inform treatment decisions in a consultation between GPs and patients, also considered that scoring a ten-minute slice of the consultation as appropriate due to the high volume of complex data produced by video-recordings. The first ten-minute segment of each video was viewed minute by minute and followed the MIPS coding informed by Ford (2000) and Kaner (2007) (see Appendix 13). Owing to the volume of utterances and non-verbal communication to be coded, each ten-minute segment took one full day to analyse. The contents of each one-minute segment were coded into modes of exchange, which are presented in Tables 6.4 and 6.5. Each of the modes of exchange were given a score of one each time it occurred within that one-minute segment.

TABLE 6. 4 VERBAL MIPS MODES BASED ON FORD ET AL (2000)

Behaviour (dependent)
Asks open question
Asks closed question
Gives information
Gives reassurance
Checks information/understanding
Directs/advises
Summarises
Interrupts
Behaviour (independent)
Orientation/instructions
Shows agreement/understanding/positive response
Disagreement/negative response
Positive exclamation
Register's information
Empathy/support
Laughs
Asks for repetition
Expresses irritation
Expresses gratitude
Expresses apology
Social conversation/personal remarks
Unintelligible
Pause

TABLE 6. 5 NON-VERBAL MIPS MODES BASED ON FORD ET AL (2000)

Non-verbal behaviour (continuous)
Nodding
Head shaking
Smiling
Touch (self)
Touch (other)
Touch (tool)
Touch (object)
Point (self)
Point (other)
Point (tool)
Point (object)
Hand gestures (illustrative)
Hand gestures (batonic
Non-verbal kinesic behaviour (dichotomous)
Shoulder position (twisted/square)
Posture (closed/open)
Body lean (backwards/forwards)
Eye contact (maintenance/avoidance)
Nurses: reading/writing (yes/no)
Nurses: touching patient (yes/no)

The combination of observing and coding the verbal and non-verbal dimensions allowed a greater yield of information strengthening the resultant analysis. It allowed the researcher to draw a clearer picture of the whole consultation between the patient and healthcare provider and to observe whether those verbal and non-verbal cues were observed and responded to by the nurse.

6.4.4.1 Patient Cues

Patients seldom express their emotions directly, but rather use cues to transmit their concerns (Uitterhoeve et al 2007). These cues are generally embedded in dialogues which

take place between the patient and the healthcare giver. It is important to recognise and respond to these cues and patients' emotional and social needs may be overlooked (Farrell et al 2005). Uitterhoeve et al (2007) carried out an observational study with five oncology nurses who interviewed an actor playing the role of a patient. Three interviews took place and approximately 20 cues were embedded in each interaction. Cue responding behaviour was assessed with the Medical Interview Aural Rating Scale (MIARS) (Heaven and Green 2001). The MIARS explores ten key interviewing skills, the number of cues and concerns the patient has and the responses of the nurse categorised into three domains(Heaven, Clegg et al. 2006). The MIARS identifies three levels of cues and how those cues are disclosed by the patient; level one is categorised into hints at an anxiety or concern; level two is where the patient explicitly expresses their concern and level three is a clear expression of emotion such as anger or crying (Heaven and Green 2001). Uitterhoeve et al (2008) classified cues into four levels; level zero involved neutral expressions, level one expression that hints at worry or concern, level two expressions which mention worry or concern and level three a clear expression of unpleasant emotion. The nurses explored about 32% of the cues, 17% were acknowledged and the nurses responded to 50% of the cues with distancing behaviour. The nurses were more likely to respond to the higher-level cues than the lower level cues. This suggests that recognising cues can be complex and therefore an interaction analysis could be limited if lower level cues are not identified. Most of the publications around cue responding behaviour has been carried out in cancer nursing, however the MIARS has been used in other specialities. Noordman et al (2013) applied the MIARS to gain insights into the perspectives of children and adolescents with type 1 Diabetes. It is also used in different parts of the world; Lin et al (2017) explored the cue responding behaviour of a cohort of 110 nurses in Taiwan. They remarked that Taiwanese nurses demonstrated more distancing behaviour (81% of the time) in relation to cue responses than in countries such as Hong Kong, the Netherlands and the UK (Heaven, Clegg et al. 2006, Uitterhoeve, Bensing et al. 2009, Chan 2014).

Zimmerman et al (2007) undertook a literature review of observational studies carried out between 1975 and 2006 which involved patient-physician consultations and reported the findings of patient expressions of cues and/or concerns. They found that most cues and concerns were missed and physicians used behaviours to avoid further disclosures. As a

result of this, Del Piccolo et al (2011) formed an international group of experts to meet and share experience and language on cues and concerns which lead to the development of a new coding system the Verona Coding Definitions of Emotional Sequences (VR-CoDES). The patient codes and concerns are defined in the VR-CoDES-CC and the healthcare provider responses are explored with the VR-CoDES-P. In this new system cues are defined as "verbal or non-verbal hints, which suggest an underlying unpleasant emotion and that lacks clarity". Concerns are described as "clear and unambiguous expressions of an unpleasant current or recent emotion that are explicitly verbalised with or without a stated issue of importance".

6.5 Ethical Considerations

Caldicott approval to undertake the video-recordings in the Trust and to ensure confidentiality of nurse and patient information, was given on 28th February 2019 (see Appendix 14). A study protocol was written as well as participant information leaflets and consent forms for the nurse and patient participants (See Appendix 15). Ethical approval was sought and approval to conduct the study was given by London-Brent Research Ethics Committee and the Health Research Authority and Health and Care Research Wales (HCRW) on 08/04/2019 Reference 19/LO/0450 IRAS Number 250427 (see Appendix 16) and final confirmation of capability and capacity to deliver the study was given by Research and Development at Northumbria-Healthcare NHS Foundation Trust on 8th June 2019 (see Appendix 17).

Consent to perform the videos was necessary from both the patient and the nurse involved. Consent was taken as per the Principles of Good Clinical Practice for Research (Guideline 2001). Before consent was taken, the participants had the opportunity to read information sheets about the study and to ask questions. On completion of the recording, consent was confirmed to ensure that nothing had been revealed during the consultation that made either the nurse or the patient uncomfortable to have the video analysed. This process was approved by the Brent and Southwest Ethics Committee and it was also given Research and Development approval by Northumbria Healthcare NHS Foundation Trust.

6.6 Sampling Strategy

As described in Chapter 5 (section 5.7), purposive sampling techniques are often used in qualitative research (Teddlie and Yu 2007) and can be defined as selecting units, namely groups or individuals, which have particular characteristics in common with the research question. The same approach was used in Phase III of the study, which also aimed at targeting nurses who had the same role of giving information about Methotrexate and may exhibit similar feelings and experiences. The sample size was based on the work of other researchers who had used video-recorded interviews. Video-recordings to inform research and improve services has been used in different healthcare settings. James et al (2020) video-recorded 14 consultations between practice nurses and patients to explore how they communicate lifestyles risks. They identified that whilst the nurses demonstrated some communication skills, they felt that there was room for further development. Brataas et al (2010) designed a study to investigate the goal-related communication between nurses and patients in cancer clinics in Norway. They selected their eight nurse participants based on purposive sampling, ie they made a judgement on who they thought would be most representative and informative. They video-recorded eight conversations between each of the nurses and a patient in one cancer outpatient department and the recordings varied from 15 to 45 minutes. They revealed that a clear goal of the nurses was to ensure the patients understood their cancer treatment as fully as possible to ensure optimal management. However, the nurses gave a lot of information in long sequences with patients responding in short utterances only and they took those responses such as “yes” or “ok” to represent understanding. This is paralleled in the findings of Phase III of this study and will be described later in this chapter.

6.7 Participant Identification

Four Specialist nurses in the Northumbria Rheumatology service agreed to be videoed. Ethics approval was given by London Brent Research Ethics Committee and the Health Research Authority on 8th April 2019 (see Appendix 16). All participants had the opportunity to read the Information Sheets about the study, and all participants gave written consent. Four Specialist nurses and ten patients took part in this phase of the project.

Ten consultations by the four Specialist Rheumatology Specialist nurses were recorded. This department was situated in a different Trust than the two Trusts which were used to recruit the nurses for Phase II of this study. Bickerton et al (2010) describes the use of video-recordings to improve the implementation of patient-centred care in consultations. They described two case studies in which the consultations were video-recorded and described in detail the communication between the healthcare professional and the patient. Bickerton et al emphasise that the video-recordings do not necessarily diagnose problems, but rather, raise awareness and increase understanding of the consultation process. Therefore, the contribution of Phase III of this study, whilst limited to ten video-recordings from one Rheumatology service, the findings add to the body of literature in this area and raise further awareness of gaps in consultation style of Rheumatology Specialist nurses who give information to patients about Methotrexate.

All participants were given information sheets about the study and given opportunities to ask questions before deciding to participate in the study. Informed consent was taken from every nurse and patient participant and the original was stored in the study master file within the Research and Development Department at Northumbria-Healthcare NHS Foundation Trust, a copy of the consent form was given to each participant. Every participant was also given the option to stop the video at any point, without having to give a reason, and that video-recording would be destroyed. No participant asked for the video recording to be stopped and all gave consent for the video-recordings to be used in the study.

6.8 Study Setting

The nurses were all known to the researcher, but in order to ensure that each participant was comfortable with the video-recorder, it was set up in the nurse's consulting room before the consultation with the patient took place. This allowed the nurse and patient participants to become comfortable with the camera. Also, the recording was started just before the consultation was initiated, which allowed the researcher to leave the room. The aim of this was to allow participants to feel more relaxed and conduct their normal consultation without an observer which could have added more pressure to the nurse and

patient and could have impacted on the consultation itself. The video recordings captured the consultation process between nurse and patient at the time the patient received information about Methotrexate. None of the patients had received Methotrexate previously.

6.8.1 Video-Recording 1

The nurse (N1) was sitting directly in front of the table, the patient was sitting in a chair at right angles to the table which meant that the patient had to turn her head to the right to see the nurse, there was another chair to the left of the patient. The desk very small and was cluttered with notes. The nurse introduced herself briefly by name only, then goes straight into talking about the pulmonary function test results.

6.8.2 Video-Recording 2

The nurse (N1) was sitting in the clinic room as video-recording 1. The patient sat in the chair at right angles to the desk and nurse. The nurse was facing the patient but her shoulders were twisted towards the desk. The patient notes were open on the desk and the computer screen showed the blood results of the patient. The patient did not appear relaxed and at times appeared unhappy and distressed. The nurse made no introductions or establish baseline knowledge of the patient. The nurse continued the consultation giving information about Methotrexate but did not appear to have a relaxed rapport with the patient. The patient appeared to want to talk about other issues, but the nurse either avoided this or did not pick up these cues.

6.8.3 Video-Recording 3

The nurse (N2) was sitting on a swivel chair in front of a large desk. The patient notes were open on the desk, and there was a filing tray and two computer screens on the desk. One of the computer screens was displaying the patient's blood results. The patient was accompanied by her mother and they sat with their chairs facing the nurse. The nurse

mostly faced the desk and wrote in the patient notes but swivelled occasionally to face the patient and her mother. The nurse introduced herself by name and her role and also established that the patient was happy to continue and to take Methotrexate. The nurse did not establish baseline knowledge with the patient. The nurse introduced the Methotrexate booklet at the start of the consultation. The patient looked slightly nervous and her mother did not speak any utterance throughout the consultation. The nurse mostly addressed the patient throughout the conversation.

6.8.4 Video-Recording 4

The nurse (N3) was in a small clinic room and was sitting in front of a small desk. The desk was cluttered with two computer screens, one of which was open to the lab results page, and there was also a set of filing trays on the desk. The nurse was sitting facing the patient, who was sitting at right angles to the desk and was required to turn her shoulders slightly to face the nurse. The patient appeared nervous, and "chewed" her lip frequently throughout the consultation. The nurse's manner was relaxed and confident. The nurse did not introduce herself or establish baseline knowledge, and she told the patient why she was there rather than ask her. The nurse's rapport with the patient was professional but did not engage in empathic conversation.

6.8.5 Video-Recording 5

The nurse (N4) was in a clinic room, again the desk was cluttered, and it was very small. It housed one computer screen and a printer, leaving little room for the nurse to write in the patient notes. She was sitting on a swivel chair which she turned to face the patient. The patient's chair had been placed so that it was facing the nurse, but it was not at right angles to the desk. The patient appeared relaxed and the nurse was smiling, which established a relaxed and friendly rapport with the patient. The computer screen was also showing the lab results page. The nurse did not introduce herself but did ask the patient if she had done any reading about Methotrexate in order to establish baseline knowledge.

6.8.6 Video-Recording 6

The nurse (N3) sat in front of a cluttered desk, and turned to face the patient. The patient notes were directly in front of her, between herself and the patient and the computer screen revealed the lab results page. The patient was at right angles to the desk, and he was leaning away from the nurse to his right. The nurse was confident, and had a professional approach. There was no attempt to establish a friendly rapport with the patient and he did not appear engaged with the nurse. The nurse did not introduce herself or establish any baseline knowledge with the patient.

6.8.7 Video-Recording 7

The nurse (N1) was sitting in the same clinic room as the video-recording 1. There were two chairs at right angles to the side of the desk, but the patient was sitting in the chair furthest away from the nurse, so there was a chair space between them. The nurse was sitting directly in front of the desk, with the patient notes open and the computer screen open to the patient blood results. The patient appeared relaxed, but hard of hearing as she leaned forwards in her chair, inclining her ear towards the nurse. The patient started the conversation by giving the nurse the results of her pulmonary function test and a list of her medication, which allowed the nurse to continue with this thread.

6.8.8 Video-Recording 8

The nurse (N3) sat in a clinic room in front of a small cluttered desk, which held a printer and computer screen, the screen was open at the lab results page. The patient notes were open on the desk in front of the nurse. She swivelled her chair to face the patient when talking to him, the patient's chair was turned from the side of the desk, so that the patient faced the nurse without having to twist his shoulders. The nurse was confident and told the patient why he was there and that he has Rheumatoid Arthritis which the patient agreed with. The patient appeared relaxed and was wearing a showerproof jacket. The nurse went straight into talking about inflammation which needed to be "dampened down", rather than introduce herself and establish a rapport.

6.8.9 Video-Recording 9

The nurse (N4) was in a clinic room, on the wall directly in front of the nurse was a poster which displayed “Ask 4 questions”, however the patient sat to the side of the poster and could not view it directly. The nurse had the patient notes in front of her and the lab results page was open on the computer screen. The patient was sitting on a chair at the side of the desk, and was leaning forwards with her arms on the desk. She was smiling and appeared relaxed. The nurse introduced herself by name and role. She also confirmed that the patient was there to start Methotrexate and asked if the patient has done any “Googling”, to which the patient affirmed that she had and the nurse went on to establish how much the patient learned from this. The nurse established a friendly rapport with the patient from the start of the consultation.

6.8.10 Video-Recording 10

The nurse (N2) was in a spacious clinic room sitting in front of a small desk with room for a computer, screen and keyboard. The nurse had the patient notes on the corner of the desk and had the lab results page open on the computer screen. The patient was sitting on a chair at the side of the desk and angled herself towards the nurse. The nurse sat on a swivel chair which allowed her to face the patient when talking to her. The patient still wore her outdoor coat and scarf. The nurse did not introduce herself, but established with the patient that she had seen her before. The nurse established that the patient had been seen by one of the consultants who had diagnosed Rheumatoid Arthritis, with which the patient agreed. The nurse was relaxed and friendly and the patient responded, establishing a friendly rapport.

6.9 Data Transcription

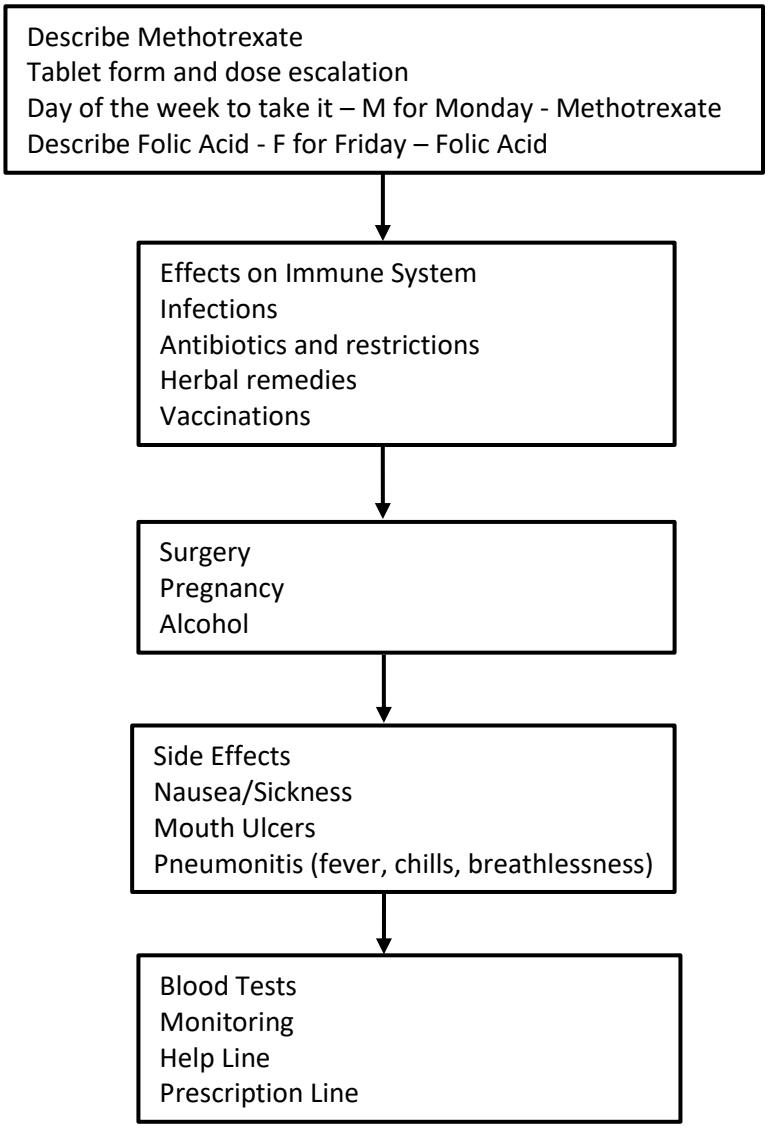
The audio-recording only was given to the transcriber and transcripts of the complete consultations were typed by the transcriber employed in Phase II of this study. The transcripts were checked for accuracy by the researcher by playing back the video-recording. All participants were offered the opportunity to review the video-recording on

completion of the consultation, however this opportunity was not exploited. The nurses were all sent copies of the typed transcripts to ensure they agreed that it reflected their consultation.

6.10 Consultation Structure

The flow of each consultation was very similar, occasionally the nurse would introduce herself by name only or also adding their job role. The general flow of each consultation is shown in Table 6.6 with very little variation between all of the nurses, and all of the nurses followed a structure of information giving guided by the Methotrexate information booklet.

TABLE 6. 6 THE CONSULTATION STRUCTURE



6.11 Analysis

6.11.1 Thematic Analysis

All of the transcripts were thematically analysed allowing a systematic identification and organisation of patterns of themes across the dataset (Braun and Clarke 2012) which has been discussed in Chapter 5 (section 5.16.1). This methodology has been used in a similar study where the researchers sought to observe and analyse the interactions between general practitioners and patients who presented with osteoarthritis (Paskins, Sanders et al. 2015).

To protect the identity of the nurse participants, minimal demographic data was recorded. The nurses were aged between 30-60 years of age. Nurses one and two (N1 and N2) had two years' experience working in Rheumatology, nurse 3 (N3) had five years' experience in Rheumatology and nurse four (N4) had 20 years' experience working in Rheumatology. None of the nurses had undertaken any formal training; they learned from each other and from Rheumatologist colleagues and they attended Rheumatology meetings whenever the opportunity arose. The patient participants were aged 25-75 years and eight participants were female and three were male. The patient demographics can be seen in Table 6.7.

TABLE 6. 7 PATIENT DEMOGRAPHICS

Patient	Age	Male/Female	Nurse Conducting Consultation
P1	62	Female	N1
P2	54	Female	N1
P3	25	Female	N2
P4	27	Female	N3
P5	46	Female	N4
P6	44	Male	N3
P7	72	Female	N1
P8	68	Male	N3
P9	42	Female	N4
P10	74	Female	N2

Each patient consultation took place in a clinic room. On every occasion, the nurse sat in front of the desk with the patient notes open in front of her. The computer screen was showing the NHS Trust's results system with the patient results displayed. Every nurse also had a Methotrexate information booklet ready to use to guide the consultation with the patient. During the consultation with the patient, none of the nurses had any interruptions.

6.11.2 Statistical Analysis

Descriptive statistics were calculated using percentages, mean values and ranges. Pearson's correlations were calculated to establish any correlations between patients "positive responses" and nurses "giving information". Correlations were also calculated minute by minute, between the items of "nurse giving information" and the patient either "nodding" or giving a "positive utterance".

6.12 Results

6.12.1 Calgary Cambridge Analysis using the Consultation Observation Tool

Each video was scored using a scoring sheet, see Appendix 18 for an example of the scoring sheet. The results of the Calgary Cambridge analysis are shown in Table 6.8, each category scored a maximum of three and the maximum possible score for each video was 42.

TABLE 6. 8 RESULTS OF THE CALGARY CAMBRIDGE ANALYSIS

Category	VIDEO										Category Mean
	1	2	3	4	5	6	7	8	9	10	
Initiating	1	0	2	2	1	2	1	1	2	2	1.4
Agenda Setting	0	0	1	1	1	0	0	0	0	1	0.4
Information/Knowledge	0	0	1	1	2	0	0	1	2	1	0.8
Ideas/Concerns/Expectations	0	0	1	0	1	0	0	0	1	0	0.3
Explanation and Content	2	2	2	3	3	2	2	2	3	3	2.4
Chunking/Checking	0	0	0	0	0	0	0	0	0	0	0
Written Information	3	2	2	2	2	2	3	2	2	2	2.2
Closing Summary	1	1	1	0	2	1	0	1	0	1	0.8
Future Plan	2	2	3	2	2	2	2	2	3	2	2.2
Structure	2	2	3	3	2	2	2	2	3	3	2.4
Clarity	2	2	3	2	3	3	2	3	3	2	2.5
Rapport	2	2	2	2	3	2	2	3	3	2	2.3
Empathy	1	2	2	2	3	1	1	2	2	2	1.8
Patient Perspective	0	1	1	1	1	0	0	1	1	1	0.7
Scores	16	16	24	21	26	17	15	20	25	22	20.2

The nurses were competent or excellent at their explanation (mean score 2.4); using written information (mean score 2.2); planning (mean score 2.2); structure (mean score 2.4); clarity (mean score 2.5) and rapport (mean score 2.3). They were variable with initiating the purpose of the consultation (mean score 1.4); and with exhibiting empathy (mean score 1.8). They were not specifically setting the agenda (mean score 0.4); gathering information (mean score 0.8); checking for understanding (mean score 0); summarising (mean score 0.8) or legitimising the patient perspective. (mean score 0.7).

The time it took the nurse to complete the consultation was available from the video-recorded data. This information was scrutinised for the amount of time the nurse and the patient were talking. Correlations between the Calgary Cambridge scores and timings were calculated using Pearson correlations. The time taken for each nurse to conduct the

consultation varied from 12:20 to 23:40 minutes (mean 17 min 34 seconds). The total number of seconds where the nurse or patient was talking are shown in Table 6.9.

TABLE 6. 9 THE PROPORTION OF TIME NURSE AND PATIENT SPENT TALKING DURING THE CONSULTATION

	Nurse Talking	Patient Talking
	Seconds (%)	Seconds (%)
Video 1	913 (75)	310 (25)
Video 2	515 (77)	163 (23)
Video 3	950 (80)	237 (20)
Video 4	705 (85)	124 (15)
Video 5	915 (70)	399 (30)
Video 6	654 (85)	118 (15)
Video 7	785 (79)	213 (21)
Video 8	655 (86)	105 (14)
Video 9	761 (69)	341 (31)
Video 10	1055 (74)	365 (26)

The nurses spent 69% to 86% of the total time talking with the patient engaging in discourse only 14% – 31% of the consultation. In the high scoring consultations, the nurse spent an average of 76% of the time talking (range 69% to 86%). In the low scoring it was 80% (75% to 85%). Correlation between the total Calgary Cambridge score and the time the patient spent talking showed a moderate albeit non-significant trend (r=0.5268, p=0.12). Correlation of the proportion of the time that the patient was talking with the Calgary Cambridge score was slightly lower (r=0.4298, p=0.22). There was a significant correlation between the proportion of time the patient spent talking and the length of the consultation (r=0.7055 p=0.02). This suggests that the patients who were engaged were prolonging the

consultation but more on their agenda and indeed there was a trend to the greater length of the consultation correlating with the better Calgary Cambridge score (r=0.4903 p=0.15).

6.12.2 Medical Interaction Process Analysis

6.12.2.1 Intercoder Reliability

Video seven was scored by the same two researchers; researcher A was the study researcher and researcher B was the Consultant Rheumatologist. The results are shown in Table 6.10.

Once complete, both researchers discussed their results. Table 6.10 shows that overall, there was consistency between the two coders with 80 - 100% agreement of the codes, except for items where there were fewer than five codes and in these instances, there was never a discrepancy of more than one. Miles and Huberman (2018) suggest that an 80% agreement of 95% of codes is acceptable and Nueuendorf (2015) regards that values over 90% would be acceptable to all. There were some minor differences in the way that agreement had been coded, but after further discussion it was agreed that it was sometimes difficult to determine between what was agreement and what was a positive exclamation, as positive responses were often very short utterances that could be barely audible such as “uh huh” or even “uh” which could explain the discrepancy. There was also a small disagreement in the way that negative exclamations had been coded for patients, but again after further discussion, it was agreed that these utterances were sometimes barely audible and could be missed. Both researchers agreed that there was sufficient concordance between the two scores to show inter-coder agreement. Table 6.11 shows which patient consultations each of the four nurses carried out.

TABLE 6. 10 INTERCODER SCORING OF VIDEO 7 FOR MIPS ANALYSIS

	Researcher A	Researcher B	Researcher A	Researcher B
	N1	N1	P7	P7
Head Nodding	53	58	116	112
Head Shaking	21	22	15	14
Smiling	6	6	5	5
Touching	45	40	34	34
Pointing	6	7	0	0
Illustrative gesture	6	5	1	1
Batonic gesture	60	60	18	19
Verbal Dependent				
Open question	0	0	0	0
Closed question	2	2	3	3
Giving information	48	47	12	13
Reassurance	5	5	0	0
Checking	1	2	2	1
Directing	0	0	0	0
summarising	1	2	4	3
Interrupting	3	3	12	11
Verbal Independent				
Orient/instruct	0	0	0	0
Agreement	26	27	91	86
Disagreement	0	0	3	3
Positive exclamation	4	4	1	2
Negative exclamation	0	0	15	11
Register info	0	1	20	19
Empathy	5	4	0	0
Laughs	4	4	9	9
Ask repeat	0	0	0	0
Irritation	0	0	0	0
Gratitude	0	0	1	1
Apology	0	0	0	0
Social conversation	5	5	5	5

TABLE 6. 11 THE PATIENT CONSULTATIONS EACH NURSE CONDUCTED

N1	**N2**	**N3**	**N4**
P1	P3	P4	P5
P2	P10	P6	P9
P7		P8	

The complete results of the coding for the ten videos are presented in Table 6.12 and the total scores of all videos are shown in Table 6.13.

TABLE 6. 12 MIPS CODING FOR VIDEO-RECORDINGS

	VIDEO RECORDING																			
	1		2		3		4		5		6		7		8		9		10	
Domain	N1	P1	N1	P2	N2	P3	N3	P4	N4	P5	N3	P6	N1	P7	N3	P8	N4	P9	N2	P10
Head Nodding	46	91	30	78	21	102	18	54	54	80	19	83	53	116	28	34	23	87	48	36
Head Shaking	10	22	15	8	8	2	15	1	13	10	11	9	21	15	6	0	10	12	10	11
Smiling	2	2	10	2	0	0	3	15	19	6	1	2	6	5	1	1	4	5	4	4
Touching	25	19	38	25	7	60	36	26	61	53	37	13	45	34	34	27	24	18	39	10
Pointing	2	0	0	6	6	1	1	0	9	0	4	1	6	0	0	0	1	0	9	3
Illustrative gesture	6	42	26	2	49	0	11	2	61	18	16	5	6	1	24	0	34	2	68	8
Batonic gesture	66	7	34	4	21	0	18	3	19	22	40	0	60	18	26	5	36	0	43	24
Verbal Dependant																				
Open question	0	0	0	1	1	0	0	0	3	0	1	0	0	0	0	0	2	0	0	0
Closed question	5	15	3	3	10	0	19	5	4	7	11	4	2	3	11	6	10	0	10	5
Gives information	43	26	34	8	50	8	41	8	33	10	62	11	48	12	35	5	85	30	49	13
Reassurance	0	1	0	0	10	0	6	1	4	0	0	0	5	0	14	0	7	1	5	2
Checks	5	10	0	0	10	0	1	0	0	0	0	0	1	2	2	1	2	0	8	8
Directs	0	0	0	0	12	0	18	0	0	0	0	0	0	0	2	0	2	1	0	0
Summarises	0	0	0	0	2	0	2	0	0	0	0	0	1	4	3	0	0	0	5	2
Interrupts	1	10	5	1	0	1	3	0	0	0	0	0	3	12	4	2	0	1	6	8
Verbal Independent																				
Orient/instruct	0	0	0	0	2	0	1	0	0	0	0	0	0	0	18	0	0	0	0	0
Agreement	18	40	1	8	2	26	21	21	5	9	7	12	26	91	6	62	14	100	24	45
Disagreement	0	1	0	1	0	1	0	5	0	1	0	0	0	3	0	1	1	4	0	3
Positive exclamation	0	0	0	0	2	47	3	1	2	8	0	0	4	1	0	0	1	1	1	2
Negative exclamation	0	0	0	0	0	1	1	2	5	3	0	0	0	15	0	0	1	0	0	0
Register's information	0	0	6	43	0	27	0	0	1	11	0	31	0	20	4	0	2	0	0	2
Empathy	1	0	0	0	0	0	0	0	3	2	0	0	5	0	2	0	0	0	0	0
Laughs	0	1	0	0	1	5	3	7	6	11	1	1	4	9	1	2	4	3	0	3
Ask repeat	1	0	0	0	0	0	2	0	1	3	0	0	0	0	0	0	0	0	0	0
Irritation	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
Gratitude	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
Apology	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Social Conversation	0	0	0	1	0	0	1	0	0	0	2	2	0	0	0	0	0	0	0	0

TABLE 6. 13 TOTAL SCORES FOR ALL VIDEO-RECORDINGS

	Total	
Domain	Nurse	Patient
Head Nodding	340	761
Head Shaking	119	90
Smiling	50	42
Touching	346	275
Pointing	38	11
Illustrative gesture	301	80
Batonic gesture	363	83
Verbal Dependant		
Open question	7	1
Closed question	85	48
Gives information	480	131
Reassurance	51	5
Checks	29	21
Directs	34	1
Summarises	13	6
Interrupts	22	35
Verbal Independent		
Orient/instruct	21	0
Agreement	124	414
Disagreement	1	20
Positive exclamation	13	60
Negative exclamation	7	21
Registers information	13	134
Empathy	11	2
Laughs	20	42
Ask repeat	4	3
Irritation	0	3
Gratitude	0	2
Apology	0	1
Social conversation	11	9

In order to investigate whether the patient positive responses were in response to the nurse "giving information", correlations, minute by minute, between the items of "nurse giving information" and the patient either "nodding" or giving a "positive utterance" were calculated. Correlations were enormously variable with r values ranging from -0.349 to +0.893. When all ten videos were combined, the overall correlation was r = +0.486 (p=0.00001). There was, therefore, a relationship between the nurse giving information and

the verbal or non-verbal positive responses from the patients. However, with an r squared value of 0.236, only 24% of the positive responses were explained by the giving of information, suggesting that the patients were making positive responses for other reasons as well.

Compared to the nurses, patients more frequently showed disagreement an average of two per consultation (range 0 – 5), whereas there was only 12 nurse disagreement across all ten video-recordings. Patients reacted with more interruptions an average of 3.5 per consultation (range 0 – 12) compared to nurses with an average of 2.2 per consultation (range 0 – 6). Patients also exhibited more negative exclamations an average of 2.1 per consultation (range 0 – 15) compared to nurses who averaged 0.7 per consultation (range 0 – 5). Patients registered information more frequently, an average of 13.4 times per consultation (range 0 – 43) whereas nurses averaged 1.3 times per consultation (range 0 – 6). Patients only occasionally express irritation, gratitude or apology a total of four times across all of the video-recordings and nurses did not express irritation, gratitude or apology in any of the video-recordings. This would be consistent with the patients reacting to the nurse dominating the encounter with their agenda of information giving.

The nurses, did more directing, summarising and instructing on average 6.8 times per consultation (0 – 21) compared to patients who had an average score of 0.7 (range 0 – 4), this was mainly summarising. Nurses exhibited more gestures of pointing averaging 3.8 (range 0 – 9) compared to patients 1.1 times per consultation (range 0 – 6) and nurses touched more per consultation averaging 35 (range 7 – 61) compared to patients who averaged 29 (range 10 – 60). Information was conveyed with empathy and reassurance by the nurses. Nurses asked most of the questions, however, and averaged 9.2 per consultation (range 3 – 19) the patient averaged 4.9 per consultation (range 0 – 15). Patients did almost as much checking of their understanding as the nurses averaging 2.1 per consultation (range 0 – 10) comparted to nurses who average 2.9 (0 – 10). Table 6.14 shows the scores for the nurses and patients when mapped against the five highest scores compared to the five lowest scores of the Calgary Cambridge scoring.

TABLE 6. 14 MIPS SCORES WHEN MAPPED AGAINST THE CALGARY CAMBRIDGE SCORES

	Nurse	Nurse	Patient	Patient
Domains	Low scoring	High	Low	High scoring
Nodding	166	174	422	339
Shaking	72	47	55	35
Smiling	22	28	26	16
Touching	181	165	117	158
Pointing	13	25	7	4
Illustrative gesture	65	236	52	28
Batonic gesture	218	145	32	51
Verbal Dependent				
Open question	1	6	1	0
Closed question	40	45	30	18
Gives information	228	252	65	66
Reassurance	11	40	2	3
Checks	7	22	12	9
Directs	18	16	0	1
Summarises	3	10	4	2
Interrupts	12	10	23	12
Verbal Independent				
Orient/instruct	1	20	0	0
Agree	73	51	172	242
Disagree	0	1	10	10
Positive exclamation	7	6	2	58
Negative exclamation	1	6	17	4
Registers info	6	7	94	40
Empathy	6	5	0	2
Laugh	8	12	18	24
Ask repeat	3	1	0	3
Irritation	0	0	1	2
Gratitude	0	0	1	1
Apology	0	0	0	1
Social conversation	8	3	8	1

Totals are given on each item for the ten-minute section analysed. The most frequent nurse utterances were in the “gives information” item, average score 48, (range 33 – 85) and the patients responses were highest in the “nodding”, average score 76 (range 43 – 116) and, verbal “positive response” items average score 41.4 (range 9 – 100). The number of nods and positive responses was far higher than the number of nurses “giving information” utterances.

The five lower scoring consultations were compared with the five higher scoring consultations. Nurses in high scoring consultations made many more illustrative gestures with a total of 236 across the five highest scoring consultations (mean= 47 per consultation)

compared to the five lower scoring videos with a total of 65 across those consultations (mean= 13 per consultation). Conversely fewer batonic movements were made by the nurses in the higher scoring consultations with 145 across all consultations (mean= 29) compared to the lower scoring consultations with 218 across all consultations (mean= 44). Nurses in the higher scoring consultations smiled more (mean= 6) and shook their heads less (mean= 9) but pointed more (mean= 5). Whereas nurses in the lower scoring consultations smiled an average of four times, shook their heads more (mean= 13) and pointed less (mean= 3). Nurses in the higher scoring consultations asked an average of one open questions, but nurses in the lower scoring consultations did not ask any open questions. Nurses in the higher scoring consultations gave more reassurance (mean= 8), and checked for understanding and summarised more (mean= 6). Nurses in the higher scoring consultations also directed and orientated the patients more, 20 times over the five consultations whereas the nurses in the lower scoring consultations only did this once across the five recordings. The nurses in the higher scoring consultations laughed more (12 times over the five consultations) but engaged in less social conversation (three times over the five consultations). They also showed less positive agreement (mean= 10) and made more negative exclamations (mean= 6). The amount of times information was given to patients was similar between the higher and lower scoring interviews, as was their head nodding.

Patients in low scoring consultations nodded (mean= 84) and shook their heads more (mean= 11); they made more illustrative (mean= 11) and fewer batonic gestures (mean= 6); they pointed more (seven times across the five consultations) and smiled more (seven times across the five consultations) but touched less (mean= 23); they asked more closed questions (mean= 6) but both the higher and lower scoring groups were similar when checking their understanding (mean= 2) but the lower scoring group interrupted more (mean= 5). The lower scoring group had exhibited no positive exclamations, whereas the higher scoring group expressed an average of 11 per consultations. The lower scoring group expressed more negative exclamations (mean= 3), they also registered information more (mean= 19) and engaged in social conversation more (average two) but they laughed slightly less (mean= 4).

There was some variation between the scores individual nurse patient consultations and are presented in Tables 6.15 to 6.18.

TABLE 6. 15 RESPONSES FROM PATIENTS TO INFORMATION GIVEN BY N1

DOMAIN	N1			Mean
	P1	P2	P7	
Calgary Cambridge Scores	16	16	15	15.6
Head Nodding Nurse	46	30	53	43
Head Nodding Patient	91	78	116	95
Gives Information Nurse	43	34	48	41.6
Shows Agreement Patient	40	8	91	46.3

TABLE 6. 16 RESPONSES FROM PATIENTS TO INFORMATION GIVEN BY N2

DOMAIN	N2		Mean
	P3	P10	
Calgary Cambridge Scores	24	22	23
Head Nodding Nurse	21	48	34.5
Head Nodding Patient	102	36	69
Gives Information Nurse	50	49	49.5
Shows Agreement Patient	26	24	25

TABLE 6. 17 RESPONSES FROM PATIENTS TO INFORMATION GIVEN BY N3

DOMAIN	N3			Mean
	P4	P6	P8	
Calgary Cambridge Scores	21	17	20	19.3
Head Nodding Nurse	18	19	28	21.6
Head Nodding Patient	54	83	116	84.3
Gives Information Nurse	41	62	35	46
Shows Agreement Patient	21	12	62	31.6

TABLE 6. 18 RESPONSES FROM PATIENTS TO INFORMATION GIVEN BY N4

DOMAIN	N4		Mean
	P5	P9	
Calgary Cambridge Scores	26	25	25.5
Head Nodding Nurse	54	23	38.5
Head Nodding Patient	80	87	83.5
Gives Information Nurse	33	85	59
Shows Agreement Patient	9	100	54.5

The lowest scoring nurse (N1) when scored against the Calgary Cambridge model gave the least amount of information (mean= 41.4) and had the highest head nodding from the patient (mean= 95). N1 also demonstrated the highest number of head nodding by a nurse (average 43). The highest scoring nurse (N4) demonstrated the highest amount of information given (mean= 59).

The time it took each nurse to complete the consultations was also available from the video-recording (see Table 6.19).

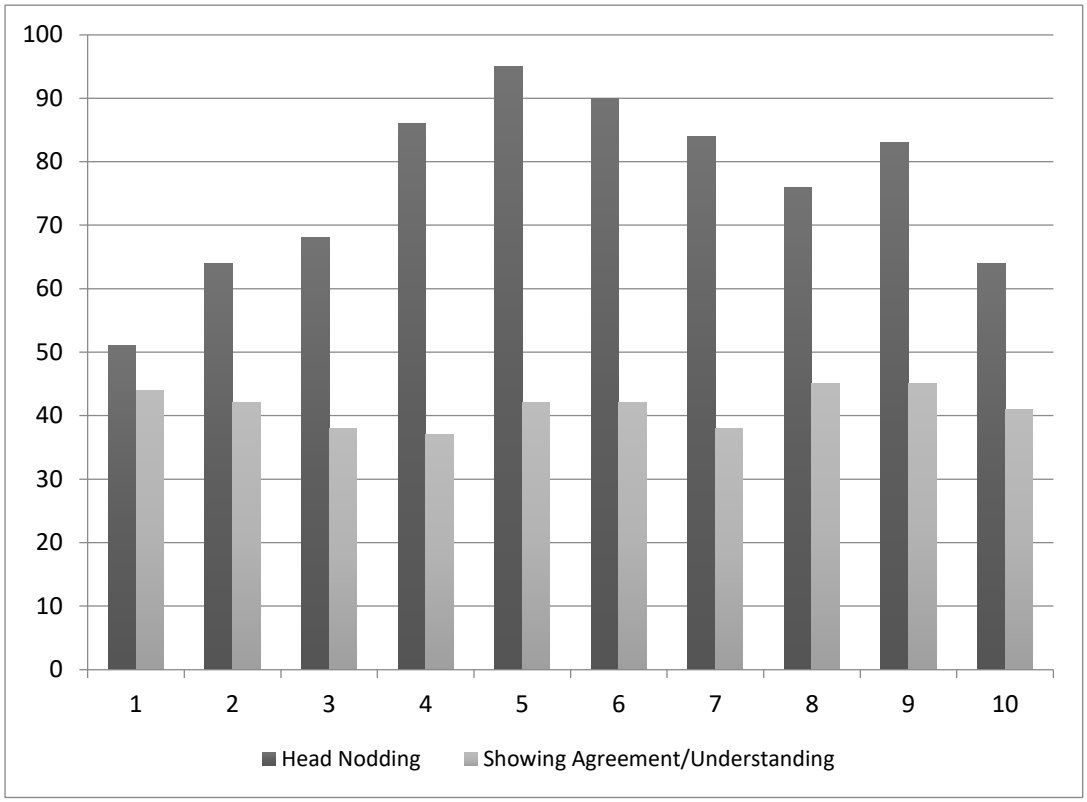
TABLE 6. 19 TIME IT TOOK FOR EACH NURSE TO COMPLETE A CONSULTATION

	N1	N2	N3	N4
P1	20:53			
P2	12:43			
P3		21:55		
P4			14:24	
P5				22:03
P6			13:20	
P7	17:41			
P8			12:42	
P9				18:28
P10		23:54		
Mean Calgary Cambridge Score	15.6	23	19.3	25.5

The two highest scoring nurses (N2 and N4) took the longest time to conduct their consultations taking an average of 22 mins 55 secs and 20 mins 15 secs respectively. The lower scoring nurses, N1 and N3 took an average of 17 mins 05 secs and 13 mins and 28 secs respectively.

The number of times the patients nodded their heads per minute and the number of times the patients showed agreement or understanding, by responding “yes” or indicating by a positive “yeah” were plotted on a chart for all patients. The results are shown in Figure 6.3.

FIGURE 6. 3 TOTAL NUMBER OF HEAD NODDING AND AGREEMENT PER MINUTE FOR ALL PATIENTS



Comparison of the totals between nurse and patient responses showed that the patients exhibit more positive responses with increased nodding and uttering positive exclamations. Some of these responses could be a response of "deference" to the perceived higher status of the nurse (Helweg-Larsen, Cunningham et al. 2004). Patients also show disagreement more and react with interruptions and negative exclamations. Patients display a higher degree of registering information and they occasionally express irritation, gratitude or apology. All of these are reactions to the information giving by the nurse and are consistent with the nurses dominating the encounter with their own agenda of information giving as described in Chapter 5 (section 5.18).

6.13 Findings of the Thematic Analysis of the Transcripts

The same researchers as described in Chapter 5 (section 5.16) analysed the transcripts. Thematic analysis was the approach used, and has been described in Chapter 3. All of the transcripts were read until the whole experience was understood (see Chapter 5 section 5.16.2) then key themes were extracted. Significant statements relating to the themes were then highlighted to illustrate the themes.

The thematic analysis of the video-recorded transcripts revealed three main themes:

- The Nurse Agenda
- Information Overload
- Missed Cues

6.13.1 Consultation Themes

6.13.1.1. Theme One: The Nurse Agenda

All of the consultations were structured around the content of the Methotrexate information booklet produced by Versus Arthritis (2019). This had the benefit of guiding the encounter, prescribing the content and providing written material for the patient.
The focus on delivering all the information in the leaflet dominated all consultations with video example of nurses cutting the patients short and taking the agenda back to the next item in the leaflet.

> P9 "….I'm just worried…in case it interacts between the drugs I take already".
> The patient gives the nurse a list of all of the medications the nurse comments:
> N4 "A nice little cocktail…"

Once all of the drugs are recorded, the nurse goes on to say:

N4 “right, brilliant, brilliant, okay so the Methotrexate is not a painkiller, it’s a disease modifying drug…”

Further indications that the patient is concerned emerged during the consultation:

N4 “you can’t have them…one is called Septrin…”

P9 “I’m allergic to it..”

N4 “…the other one is Trimpethprim…”

P9 “I’m allergic to it…”

N4 “Perfect, so you are never going to have that problem”

Finally, it emerges during the consultation:

P9 “…they said that about the iron infusion I had as well, I had an anaphylactic shock with that...I nearly died…”

This could be the reason why the patient was so anxious about drug reactions, and the nurse’s response appears to demonstrate that she understood this anxiety, but the nurse goes on to remark:

N4 “Well, I haven’t heard of anybody yet having anaphylaxis…and I don’t want to hear about it either”.

P9 “No and I’d rather it not be me…”

The nurse may be trying to reassure the patient, but equally, the nurse is dismissing the patient’s anxiety and does not provide any further reassurance. It is also clear, that the response from the patient indicates continued fear and anxiety.

In another scenario, the nurse agenda extended to almost insisting that the patient had an Intra Muscular injection of steroid when the patient clearly preferred the tablets:

N3 “do the injections work [steroid injections]…”

P4 “I haven’t had one..”

N3 “You haven’t had one of those? Right..”

P4 “I didn’t fancy one of them”

N3 “Okay, we could probably do that today….”

P4 “I’d really rather have the tablets…”

Nurse N3 goes on to acknowledge this, but further remarks:

N3 “Dr ---- is not actually here today so if I can’t get one [a prescription] it might be another option rather than you come off it [oral prednisolone] then go back on it …Okay…have a think about it…”

This exchange appears to have been driven by the difficulty the nurse would have had to get a prescription signed for the oral Prednisolone.

6.13.1.2 Theme Two: Information Overload

The amount of information given to patients during a consultation can be considerable and the nurses were aware of this, as often at the end of the interview the nurse frequently acknowledged that a lot of information had been given that the patient could not have taken in:

N3 “Okay, I’ve just kind of bombarded you there…so if you think of anything else feel free to give me a ring next week and we can explain anything with you…”

N1 “If I’ve spoken too fast and you are not too sure then ring…”

P2 “it’s a lot to take in…”

N1 “Oh there is a lot……side effects are the…so nausea is the most common, it normally settles as your body gets used to it…” “…breathlessness, fevers and chills can happen……”

However, in order to ensure that the patient could get more information if they wished, further educational opportunities through a help line were usually offered:

P5 "…if I've got any problems I won't hesitate to give you a call…"

N4 "It's what we are here for though…"

6.13.1.3 Theme Three: Missed Cues

The third theme to emerge from the data was missed cues from the patient, opportunities for the nurse to explore patient cues were missed because the primary objective of the consultation was to deliver all the information contained within the Methotrexate information leaflet:

P1 "I really want to get off this…I really do want to get off [oral prednisolone]"

N1 "In terms of your symptoms, how are you doing, have you had any visual disturbances and blurred vision"?

P1 "I have a cataract…"

N1 "Right, so, Methotrexate education…"

P2 "…I can't yawn properly…you know when you yawn you open your whole mouth…I can't do that anymore…"

N1 "Right, so I will give you the prescription and we will see you again in two weeks…but if there's any issues ring the helpline".

P8 "I'm doing badly, I mean you do all the training and you don't seem to get any fitter you know….because I was thinking about packing it all in…"

N3 "Well, let's see how this goes and you might just still be able to do it, alright, where did we get to…"?

However, there were occasions where the cues were recognised, and the nurse was within her sphere of knowledge and experience and therefore dealt with the cues well:

P9 "Now with my knees and my joints are just…my fingers…even picking up a pen…"

N4 "Have you seen an Occupational Therapist"?

P9 "No, I haven't".

N4 "I can refer you there…"

P8 "I feel like my whole body is breaking down…"

N3 "Right, so we need to get you some semblance of normality…"

6.14 Discussion

The Calgary Cambridge Model is used in many medical schools to teach students how to carry out a consultation (Kurtz, Draper et al. 2017) and is widely practised amongst GPs (Burt, Abel et al. 2014). This model emphasizes the need to provide information in manageable chunks and to use the patient's response to guide the consultation (Kurtz, Silverman et al. 2003). Whilst this model was developed for the medical profession, some attempts have been made to apply it in the nursing context (Munson and Willcox 2007). Whilst nurses who talk to patients about Methotrexate do not necessarily need to apply the full model, elements of it could enhance their consultation skills for this particular role (Munson and Willcox 2007). Patients also have different preferences for communication (Macdonald, Stubbe et al. 2013) and, to optimize concordance, the nurse needs to be able to identify the patient's information preference and meet it.

The videos of ten nurse consultations were analysed from two different perspectives; comparison with a standard consultation model and analysing thematic analysis of the transcripts. Ten videos were considered a pragmatic number for the pilot study.

It is clear that the interaction between the nurse and patient is complex and no single analysis would pick up all of this complexity. Therefore, different analyses were used. The results show that a lot of the consultation and information transfer works safely and well. The patients were informed of the important facts and processes, given written information for further reading, and all have a clear invitation to telephone call for further support and clarification. However, it appears that opportunities to address the patient agenda are missed because cues from the patients are being missed or ignored. This is considered further in the discussion section of this Chapter. There is evidence that consultations, which address the patient agenda, result in improved patient satisfaction (Carter and Berlin 2003). The missing of cues seems to be driven by an overriding need for the nurse to prioritise information giving which, could be driven by time pressures.

The data on the time each participant spent talking suggests that the involvement of the patient, which resulted in higher scoring on the Calgary Cambridge scale, added to the length of the overall consultation. It was clear that during each consultation, the type of information given was consistently similar, and took a similar amount of time to deliver; this would explain why the “extra” involvement of the patient did add some time. However, there is evidence that recognising and dealing with cues can save time by focussing the consultation on the important items (Silverman 2008), which may save time at subsequent visits. It is therefore clear that education and training for nurses in this role could result in more satisfactory and more efficient consultations.

Nurses were good at structuring the consultation, establishing rapport, giving information and instructions, all of which are central nursing skills. The content, flow and chunking of the consultation was consistent, driven by the use of the patient information sheet. The nurses missed opportunities to explore the patient’s expectations, concerns or needs throughout the consultations. The overarching aim of the consultation was to deliver information, using the Methotrexate information leaflet as a guide. The nurses speaking for between 69 and 86% of the time supports this.

Nurses were variable at assessing pre-knowledge and overlooked openings to evaluate the patient's understanding of information during the consultation. Patient feelings about the drug were sometimes offered by the patient but not often explored by the nurses. Some patient cues were missed. A lot of the patient head nodding may not have reflected understanding, but it may have encouraged the nurses to perceive this as understanding, which resulted in missed cues.

The interaction in any consultation is complex with a mixture of verbal and non-verbal behaviours and how these interactions are accommodated in a consultation is important to patient-centred care (James, Desborough et al. 2020). Tailoring verbal and non-verbal messages to patients can have a positive impact on their individual coping, emotional and comprehension needs (D'Agostino and Bylund 2014). The involvement of patients in a clear and tailored communication can improve patient care, satisfaction, trust and engagement in other health outcomes (Desborough, Phillips et al. 2018). The consultations in Phase III had a very specific purpose of transferring knowledge to a patient and Phase II, the semi-structured interviews study, (Chapter five) showed how much the nurse agenda to give this information dominated the interaction without exploration of the patient's agenda. Ospina et al (2019) conducted a secondary analysis of 112 video-recordings of clinician-patient encounters which had been carried out to assess the use of shared-decision-making tools in clinical practice. Sixty-one of the recordings had been carried out in Primary Care and 51 in Secondary Care. The secondary analysis showed that the patient's agenda was elicited in 40 (36%) of the total encounters, more often from Primary Care (30/61 49%) than secondary care (10/51 20%). They also found that interruptions occurred early in the encounter and patients were given little time to express their perspective. The analysis of the Phase III video-recordings appears to support Ospina et al (2019) in that the giving of information from the nurse to the patient was dominated by the amount of instruction and information that the nurses gave. The nurses asked the patients some questions which were related to their disease and current treatment, but there was little evidence of the nurse 'checking' the patient's comprehension or tailoring the consultation to what information the patient would have liked to have received. A further observation from the analysis revealed that the patients were more likely to check their own understanding with the nurses, but this occurred infrequently throughout the course of all of the consultations. The qualitative

analysis showed that the opportunities to ask questions were infrequently presented to the patients during the consultations, and the use of the information leaflet by the nurses to guide them during their encounters, could have introduced some inflexibility which may have further restricted opportunities for the patients to ask questions.

In response to the nurse giving information, the patients appeared to nod in agreement, this occurred frequently throughout all of the consultations. It is generally considered that head nodding represents showing agreement and understanding (Morris 1977, Petukhova and Bunt 2009, Thepsoonthorn, Yokozuka et al. 2016). However, Helweg-Larsen et al (2004) conducted a study of students in a classroom situation with a Professor. The expectation was that males would nod less frequently than females as this is a well-established observation (Dixon and Foster 1998). But this was not the case, in the classroom situation the males nodded as much as the females, which was interpreted by Helweg-Larsen et al (2004) that the Professor was dominant, and the students held a lower status. The results of the MIPS analysis on the ten videos between the nurses and patients also show a high degree of head nodding by the patients, compared to indicating agreement and understanding. This head nodding behaviour could represent a similar situation where the nurse holds a higher status as the knowledge holder. What could be of particular importance is the nurse's perspective of this. The nurse may have regarded this nodding behaviour as confirmation of understanding, which allowed them to continue their agenda regarding information giving, without feeling the need to stop to check understanding and this may have accounted for some missed cues. It is possible that the head nodding by the patients may have been in response to their perception of the nurse being in the dominant position, (Helweg-Larsen, Cunningham et al. 2004) and therefore they portrayed a deferential response. Ong et al (1995) believe that only 7% of effective communication is verbal, 22% is conveyed by the tone of voice and 55% is through visual cues. Therefore assessing and recognising cues such as head nodding are important skills as they can be linked to higher patient satisfaction, compliance and positive clinical outcomes (Crane and Crane 2010).

Conversational hand gestures are movements of the hands which occur when an individual is speaking, they are often unconsciously produced (Jacobs and Garnham 2007). The analysis of Phase III showed that those nurses who scored higher in the MIPS analysis were

using more illustrative gestures to communicate. Studies have found that using illustrative gestures during speech help to improve the addressee's attention and thus accuracy of understanding (Maricchiolo, Gnisci et al. 2009). Further, Cook (2018) considers that there is robust evidence to reveal the beneficial effects of conversational gesture on learning via a variety of cognitive processes such as memory, attentional and perception.

The amount of information given and the content of the information was similar between all of the consultations which may suggest that this was a standard part of the interaction and was dictated by the flow of information contained in the Methotrexate information leaflet.

Ford and Hall (2004) carried out a study of skilled and less skilled oncologists. They video-recorded ten oncology consultants who were considered to be skilled professionals and ten consultants who were considered less skilled. They analysed the videos using the MIPS. They concluded that the more highly skilled doctors had a significantly higher focus on disease, psychological and physical status of the patients. Indicating that their consultations had a higher degree of patient focus which considered individual care. The more highly skilled consultants asked more questions, did more checking and summarising of information to ensure the patient understood and their consultations only took three minutes longer. A weakness of this study was that the oncologists were categorised, in terms of their skills and experience, on the opinion of one of the researchers. However, the study does highlight several important points; that effective consultations skills identifying individual patient problems could lead to higher patient satisfaction (Maguire and Pitceathly 2002); training courses will improve skills and consultations adopting effective techniques do not necessarily take more time. The results of Phase II of this thesis, indicated that the nurses perceived that a time limited consultation impacted on their willingness to encourage patients to ask questions and used words such as "interrupt" if a patient did ask a question. Thus, this perception of time pressure may have been a catalyst for the nurses' agenda to become the focus of the consultation resulting in a lack of opportunities for patients to ask questions or discuss concerns. Table 6.19 above shows that there was no statistical difference between the time it took the nurse to complete each consultation and their Calgary Cambridge score. The possible implications of this will be further discussed in Chapter 7.

6.15 Limitations

This was a small study and the video recordings were of nurses from one Rheumatology service, therefore it does not necessarily reflect the wider national perspective. However, the national questionnaire, Phase I of this study, does indicate that most nurses receive no training to conduct this role, of giving information to patients about Methotrexate. Phase II further indicated that nurses, had their own agenda which was constrained by perceived time pressures, which resulted in rote type consultations with little emphasis on individualise patient care. Therefore, whilst this is a small study, it does add to the limited body of knowledge around how nurses give information about Methotrexate and how they conduct their consultations.

6.16 Conclusions

Quantitative data can be extracted from the videos and it largely supports the qualitative findings. Whilst the nurses conducted their consultations professionally and generally attempted to establish a rapport with the patients, their techniques could be improved with further training. All nurses gave adequate information about Methotrexate, as they had the booklet to guide them, but it was not tailored to suit the patient and there was no shared decision-making with the patient. Improved consultation technique could also help the nurses to interpret patient behaviours that indicate the patient's agenda and what is important to that person, as cues are often missed or ignored.

Chapter 7: General Discussion, Conclusions and Further Recommendations

7.1 Chapter Overview

The final chapter of this thesis will first restate the overall aims and objectives of this study and how they were fulfilled. An overview of the findings from each of the three phases of the study and how they add to the extant literature will then be discussed. Following this there will be a discussion of how these findings contribute to original knowledge and the implications of this to practice. There will be a discussion of the limitations of the findings followed by recommendations for further research and concluding remarks.

7.2 Study Aims and Objectives

7.2.1 Overarching Research Question

How do Rheumatology Specialist nurses gain knowledge about consulting with patients on Methotrexate and do they deliver the information to patients using a consultation technique, further can elements of their consultation be identified for development?
Which was investigated by:

- Investigating, using a survey, the processes which nurses undertake to become knowledgeable about consulting with patients on Methotrexate and to understand how much knowledge and confidence they have in giving this information.
- Exploring, through semi-structured interviews, the nurses' experiences and perception of the delivery of information about Methotrexate to patients.
- Identifying, through video analysis of consultations, the processes used by the nurses in their consultations with patients when giving information about Methotrexate and how the consultations may be further developed using the Calgary Cambridge model.

The underpinning research philosophy was based on the three dimensions of critical realism using a mixed methods approach to collect the data and a phenomenological methodology to analyse the data.

7.3 Conspectus/Study Overview

This study contributed to the understanding of how Rheumatology Specialist nurses give information to patients about Methotrexate. It has developed the understanding of how these nurses conduct this role in their consultations and provided multiple original contributions to the extant literature. Thus, the purpose of this chapter is to bring together the findings of the three phases of this study, to identify the key messages and knowledge that has been revealed through this study and to discuss recommendations for future research, education and practice.

The core findings of this study on how Rheumatology Specialist nurses gained knowledge about consulting with patients on Methotrexate and how they delivered the information to patients will be presented under the headings below:

Summary of Findings of Phase I: The National Survey

Summary of Findings of Phase II: The Semi-structured Interviews

Summary of Findings of Phase III: The Video-Recorded Nurse Patient Consultations

7.4 Summary of Findings of Phase I: The National Survey

7.4.1 Phase I Aims

The aims of the national survey were to explore the training that Rheumatology Specialist nurses had received for educating patients about Methotrexate. Further, to identify their

confidence in conducting this role and to evaluate their knowledge around clinical situations relevant to Methotrexate use. The aim of this is to reveal if any further training is required.

7.4.2 Phase I Objectives

1. To obtain data regarding training, qualifications and experience through a national questionnaire.
2. To gauge nurses' views regarding confidence and the time it takes to become confidence in conducting this role.
3. To assess levels of knowledge Rheumatology Specialist nurses, have about Methotrexate.

In response to the aims and objectives of Phase I, the findings identified that there was no gold standard training for nurses to conduct their role of giving information about Methotrexate to patients. Nurses responded that their training mostly consisted of learning from their peers or sitting in on clinics with Rheumatology consultants. Nurses were competent in their responses to multiple choice questions about Methotrexate, but their confidence in this role increased over time and there was overall agreement that more training would be useful. The findings also revealed that nurses commonly used written information to guide their consultations, this was in the form of the Methotrexate Information Booklet produced by Versus Arthritis(2019), or in-house written information and checklists.

A review of the literature in Chapter 2 revealed that there was little uniformity regarding the way nurses are trained to carry out their various roles in Rheumatology (Goh, Samanta et al. 2006, Royal College of Nursing 2009) and that there were few opportunities for nurses to enrol on a specific Rheumatology training course (Royal College of Nursing 2009). Further, the review highlighted the paucity of literature regarding how nurses are trained to meet the needs of their specialist roles in Rheumatology. However, more recently, since the study presented in this thesis was conducted, the Royal College of Nursing Rheumatology Forum has recognised that there is a lack of uniformity in the Rheumatology Specialist role across the UK and have gone some way to address this gap in the form of producing

competencies (Royal College of Nursing 2020). Nonetheless, the findings of the national survey forming Phase I of this study did highlight clearly the variability of training that nurses are given to undertake their role. Most nurses learn "on the job", from their peers and from Rheumatology Consultants. Keele University offers an MSc course in Rheumatology Practice thus those nurses who were fortunate to live nearby, could access dedicated training, but most nurses would not be able to access this due to location and limitations of numbers of students on the course. Further findings revealed that approximately 5% of nurses had undertaken a prescribing course, but this was not specific to Methotrexate. Thus, most nurses used either the Versus Arthritis booklet or in-house leaflets to guide their consultations and ensure that the pertinent information about Methotrexate was given to the patients. The researcher's own experience conducting this role was "here is the leaflet, go and tell that patient about Methotrexate" which may not be unique.

Whilst there is a dearth of literature regarding the confidence nurses have in their roles as Rheumatology Specialist nurses, Cross et al (2014) conducted an electronic survey of 576 nurses investigating confidence, training and knowledge in ostomy care. They revealed that confidence was greater in nurses who had undertaken more training and had more experience. They regarded the greatest barrier to confidence was the lack of knowledge in their specialist area and thus concluded that opportunities for continuing education would improve confidence in nurses. The study survey in this thesis whilst the sample was smaller, revealed similar findings, that it takes three to 12 months for a nurse to feel confident, which also indicates that nurses are performing this role without confidence for significant periods of time; confidence developed through experience and also through gaining knowledge as a result of training. This supports Cross et al (2014) that improving training could lead to nurses gaining confidence earlier, thus improving the experience of both nurse and patient. The need and desire for more training was a finding in both the survey and the following Phase II, the semi-structured interviews.

7.5 Summary of Findings of Phase II: The Semi-Structured Interviews

7.5.1 Phase II Aim

To explore the nurses' experiences and perceptions of the delivery of information about Methotrexate to patients, using semi-structured interviews.

7.5.2 Phase II Objectives

1. To explore the training nurses had in order to carry out their role of giving information to patients on Methotrexate and how useful this was.

2. To understand how confident nurses are carrying out this role and how they feel about the training they had.

3. To understand how nurses, use written information to inform their consultations.

4. To explore how nurses, respond to patient cues putting them at the centre of care.

Phase II of this study explored the experiences and perceptions of six nurses who gave information to patients about Methotrexate through audio-recording semi-structured interviews. (Rhee, Von Feldt et al. 2013) Phase I revealed that the use of written information to guide consultations was universal, and it was usually the Versus Arthritis leaflet (2019) but some nurses also used locally written in-house material. The written information had many beneficial effects: it structured the encounter and ensured that the necessary content was covered; it "chunked" the information into usable amounts and the local information gave clarity of monitoring and follow up. It also, however, had some negative effects: it facilitated the nurses' agenda taking priority and the nurses returning to the leaflet for the next item; it led to a feeling of overloading the patient with information and in the interviews the nurses expressed that it restricted the opportunities for the patient to ask questions.

The nurses perceived that the challenges of time pressure resulted in little opportunity for patients to ask questions, or if they did, the nurses sometimes went "off-track" with the

flow of their consultations. The nurses recognised that different patients had different learning needs, but it was not apparent that the nurses were tailoring their consultations to meet these different needs. There was agreement between all of the nurses that they had picked up knowledge and skills "on the job", and this was achieved through watching peers and Rheumatologists in clinics, but they were all in agreement that structured formal training would have been more appropriate and would have had a positive impact on their knowledge, confidence and skills. The lack of formal training may not have armed the nurses with consultation techniques which focus on the individual needs of the patients. As a result of this, it was unclear how nurses ensured that patients understood the information given to them and whether a shared decision-making process was adopted during the consultation. Thus, Phase III of the study aimed to investigate more closely how nurses conduct their consultations, how they engaged the patients in that process, how they used open and closed questions during their encounter with patients and whether the nurses recognised and responded to verbal and non-verbal cues from the patients, which is discussed in the next section.

7.6 Summary of Findings of Phase III: The Video-Recorded Nurse Patient Consultations

7.6.1 Phase III Aims

To investigate how nurses, deliver information about Methotrexate to patients, and how they ensure that patients have received and understood that information during the consultation process.

7.6.2 Phase III Objectives

1. Explore the applicability of the Calgary Cambridge consultation model and whether it can be modified for use in Rheumatology nurse patient consultations.

2. To understand the processes nurses, use in their interaction with the patients when giving information about Methotrexate.

3. To understand the processes nurses, use to ensure that patients have understood the information given.

Analysis of the videos revealed that during the consultations the patients were generally not involved in the process of shared decision-making which supports the findings of a systematic review (Légaré, Adekpedjou et al. 2018). This generic systematic review of 87 studies showed that whilst healthcare professionals were aware of the benefits of shared decision-making it was not necessarily put into practice. Two studies by Mathijssen et al (2020; Mathijssen, Vriezekolk et al. 2020) also supported this conclusion. These studies explored the knowledge of healthcare professionals in Rheumatology around shared decision-making, but there was only a low to moderate level of shared decision-making put into practice. These studies do suggest that the existing evidence around the application of shared decision-making could apply to nurses' consultations when giving information about Methotrexate and could indicate the need for further specific research in this area. The findings of the video-recordings revealed that the patients' ideas, concerns and expectations were not explored and their understanding of the information given to them was not checked by any of the nurses. Further, whilst the nurses interviewed in Phase II of this study agreed that individual patients have different learning needs, the findings of Phase III showed that tailoring the consultation to meet individual needs was not adopted during the consultations. The Methotrexate leaflet (Versus Arthritis 2019) guided the consultations for all four nurses. This was used as a checklist to ensure that all information was given to the patients. Phase I revealed that checklists were commonly used by nurses during their encounters with patients, and the findings of Phase II showed that nurses described having a "speech" or "spiel". Phase III showed that nurses used the Methotrexate leaflet to guide their consultation agenda in a rote fashion leaving little opportunity for the patients to be part of this process.

Nurses were allocated ten-minute appointments to complete their consultations and thus perceived they had time pressures. This perception of time pressure was also a finding of the semi-structured interviews in Phase II, which resulted in a focus on the transfer of

information which may have been at the expense of involving the patient in the consultation. This perception of time limits, may have been the reason why only seven open questions were asked by the nurses during all ten of the video-recordings. However, the evidence on shared decision-making does not support the claim that it adds more time to a consultation (Légaré and Thompson-Leduc 2014). A Cochrane systematic review analysed 115 shared decision-making aids, ten of these measured the length of the consultation. Two of the studies indicated that the shared decision-making intervention took slightly longer time to conduct the consultation, however they found that in six studies there was no difference in the length of the consultation (Stacey, Légaré et al. 2017). Thus, the shared decision-making tools have a variable impact on the consultation and this could be a consideration when assessing time implications.

Missed cues were also a significant finding. The reasons behind missing these cues could have been either avoidance through perceived time pressures, lack of confidence in being able to address the concern raised or they were simply not picked up by the nurses. It is also possible that some cues may have been overlooked because the nurses were receiving positive reactions from the patients in the form of head nodding and positive utterances. These may have been interpreted by the nurses as positive understanding from the patients, but these reactions may also have been deferential responses by the patients which does not necessarily indicate understanding (Thepsoonthorn, Yokozuka et al. 2016). A number of studies explore missed verbal cues, or opportunities for further discussion during a consultation (Ahluwalia, Levin et al. 2012, Hsu, Saha et al. 2012) and it has been suggested that a physician's ability to detect emotional cues leads to higher patient satisfaction (Blanch-Hartigan 2013). Blanch-Hartigan further reports that training of physicians has almost exclusively been focussed on the meaning of emotional cues rather than the detection of them. Most research regarding missed cues have been conducted with physicians, and they are generally in the area of Oncology. However, a study by Jansen et al (2010) investigated how nurses respond to emotional cues of cancer patients. A total of 105 cancer patients were video-recorded during an educational consultation with a nurse, and the patients completed a recall questionnaire. They used the Medical Interview Aural Rating Scale (MIARS) (see Chapter 6) to rate the consultations and found that the most common response to emotional cues was distancing (35.8%) followed by

acknowledgement (29.5%). However, nurses responded to the majority of informational cues (65.7%). Patient recall was negatively influenced by distancing responses. The limitation of the MIARS is that it relies on verbal cues and does not consider the non-verbal cues that patients exhibit, thus the findings of the study presented in this thesis reflect a novel approach in that the non-verbal cues were analysed using the MIPS and is described further below.

The literature review for this thesis (see Chapter 2) revealed that the utilisation of consultation techniques which would enhance the nurses' understanding of body language and utterances is relatively understudied for nurses. The training of consultation techniques is much more widely adopted in the medical field (Butler 1992, Coleman 2000, Neighbour 2004, Paskins, McHugh et al. 2014). Brataas et al (2010) audio recorded the conversations between eight nurses and patients in an Oncology outpatient department. The recordings were analysed and three core themes emerged around treatment plans, prognosis and psychosocial reactions. They found that discussion around each theme varied depending on the needs of the patients, however when it came to information giving, the discussion was structured around the headings of a booklet, and during this time the communicative activity of the patients was minimal. A clear goal of the nurses was to help the patients understand their treatment plan to ensure optimal management, and these were proposed by the nurse rather than through agreement with the patients. Brataas et al (2010) concluded that more attention needs to be given to how nurses communicate and negotiate these goals with the patient, indicating that consultation technique is an important contributory factor to achieve the optimum nurse patient experience. Further, the specialist area investigated by Brataas et al (2010) was Oncology, but the findings of their study are supported by the findings of Phase III of the body of work presented in this thesis, suggesting that nurses use written material to support their consultations in other specialist areas. This viewpoint is supported by the work of Macdonald et al (2013) who video-recorded the consultations of ten nurses in primary care and they concluded that checklists and written material were extensively used during their discourse with the patients and was driven by the nurses agenda. Thus, Phase III of the study presented in this thesis makes a significant contribution to the extant body of work in this area by highlighting that the use

of written material and the domination of the nurses' agenda during a consultation with patients, may be occurring more widely in different specialist areas.

7.7 Methodological Considerations

The methodological considerations of Phases I and II have been extensively discussed in Chapters 4 and 5. As the nurse-patient interaction being scored in the project was a much more limited interaction which involved a specific aim of ensuring a patient had the information required to ensure they took the medication safely and as prescribed, it meant that not all of the items on the COT were relevant. There has also been previous discussion in the literature review, reasoning that the Calgary Cambridge consultation model (Denness 2013) could be applied to the nursing scenario. Whilst the Calgary Cambridge model was originally designed for healthcare professionals in primary care, its patient-centred approach helps to build trusting relationships and can be adapted to suit a nursing model (Fawcett and Rhynas 2012). Themes for scoring the consultations was based on the Calgary Cambridge model and was specifically developed for this study. Themes around physical examination and gathering information to contribute to a diagnosis were removed as these did not apply to the nurse consultation. The themes were scored using the scoring system of the COT.

Whilst the Calgary Cambridge consultation model provided the structure on which to analyse the interaction between the nurses and patients, it did not specifically provide a structure with which to analyse the non-verbal behaviour and utterances of the nurses and patients and thus cues to the patients' agendas could be missed (Butler 1992). In order to address this and explore in more depth the interaction between the nurses and patients, the Medical Interaction Process System, (MIPS) was adopted, which was developed by Ford et al (2000) and was based on the work of Roter (1991). It is a tool that allows the researcher to analyse and code verbal and non-verbal interactions between the doctor and the patient. This tool was developed to be applied to the field of Oncology where the conveyance of information can be distressing to the patients and the clinicians. It is therefore of the utmost importance that the information which is being conveyed is being delivered sensitively and successfully in order to ensure that the patient has received the

information accurately to reduce stress and anxiety. The MIPS has been discussed at length in Chapter 6, however it was adopted as the method of choice for the video-analysis as it incorporates the observation and scoring of all aspects of the interaction between nurses and patients during the consultation as described in the previous section, which resulted in richer data analysis. Each specific utterance or non-verbal behaviour of the nurse and patient in a ten-minute segment of the consultation was counted resulting in a score which provided quantitative data. The integration of this method provided a distinctive opportunity to use a novel method in the analysis of video-recordings of nurse/patient consultations in Rheumatology. This method has not been used in this context before and it gave the researcher a unique opportunity to observe and analyse, in fine detail, how nurses conduct their consultations when giving information about Methotrexate to patients. Whilst this was a very time-consuming analysis method, the added dimension of exploring the non-verbal behaviours of both nurse and patient highlighted that cues were frequently missed or ignored. This supports the viewpoint that the nurses' own agenda dominated, which resulted in missing non-verbal cues from patients indicating that they also had their own agenda that they wished to explore.

7.8 Original Contribution to Knowledge

There are currently no identified studies for direct comparison in this area of research and therefore, this study contributes to our understanding of how nurses give information to patients about Methotrexate during their consultations in a unique and original way.

Some of the initial results of this study were presented at British Society of Rheumatology Annual Meeting in 2015 (Robinson, Ryan et al. 2015), the findings from Phase I and II have been published (Robinson, Hassell et al. 2017, Robinson, Ryan et al. 2018) and some of the findings from Phase III using the Calgary Cambridge scoring and MIPS analysis have also recently been published (Robinson, Scott et al. 2021). A fourth manuscript describing the findings of the MIPS analysis is currently being prepared to submit for publication later in 2021.

7.8.1 Original Contribution from Phase I

7.8.1.1 Training

The findings of Phase I revealed that most of the nurses who completed the online survey had not received any structured training to conduct their role of giving information to patients about Methotrexate. A total of 31.5% (n=23) of respondents learned by observing peers and doctors, 25% (n=18) described self-directed learning and 15% (n=10) observed Rheumatology clinics. This highlighted the lack of training Specialist nurses in Rheumatology receive to conduct their roles. There is little in the literature around Rheumatology nurse training, the RCN conducted a survey of this role (2009) which emphasized the extent of the Specialist nurses role in this field, but it did not expressly review the way in which nurses are training to conduct this role. The RCN went further by producing a competency framework for Rheumatology Specialist nurses (2020), thus recognising the need for a national standard for Rheumatology Specialist nurses to work toward, but the implication is that the nurses have to use their own resources to achieve these competencies. The findings of this study confirms that there is no standard national training for Rheumatology Specialist nurses, which can also be seen in other specialist areas and that the onus is often on the nurse to further their own post graduate education in specialist roles (Dury 2014, Cook, McIntyre et al. 2019).

7.8.1.2 Confidence and Knowledge

The findings from Phase I suggested that nurses had a reasonable knowledge of Methotrexate based on common clinical scenarios, which does indicate that nurses do seek out information themselves. In terms of confidence, 60% (n=51) of the nurses were very confident in their role, however this confidence was related to how long they had been conducting this role and confidence increased over time. There are few surveys which explore nurses knowledge and confidence in their role, Courtenay and Carey (2008) conducted a survey of diabetes nurses who were nurse prescribers, with the aim of

investigating how educationally prepared the nurses were to carry out this role. Whilst all of the nurses had taken a prescribing course, almost half had not undertaken a diabetes course and their training consisted of in-house training and learning from peers and doctors, further 50% of the respondents felt underconfident in their role. The findings of Phase I supports these outcomes, but further adds to the extant literature as it is the first study to examine the knowledge and confidence of Rheumatology Specialist nurses in their role of giving information about Methotrexate to patients.

7.8.1.3 Written Information

Phase I further provided an original contribution to knowledge by highlighting the extent to which Rheumatology Specialist nurses may be using written information to guide their consultations with patients. The Methotrexate Information Booklet (Versus Arthritis 2019) was widely used as well as checklists and information produced by the National Rheumatoid Arthritis Society, which was preferred by 26% (n=23) of respondents. There are few studies which specifically describe the use of written materials by nurses in their consultations, but a study by Macdonald et al (2013) reported the extensive use of checklists and written materials by diabetes nurses during their consultations. However, this study was not a national survey, but video-recordings of ten nurses in primary care. Therefore, the findings from Phase I add original knowledge to the extant literature supporting the limited research that has been conducted in this area.

7.8.2 Original Contribution Phase II

Phase II consisted of semi-structured audio-recorded interviews with six Rheumatology Specialist nurses from two different Rheumatology services. The typed transcripts were analysed and four main themes and two sub-themes emerged which will be discussed below regarding their contribution to original knowledge.

7.8.2.1 Theme One: Using Written Information to Structure the Content of the Consultation

All of the nurses interviewed used the Methotrexate Information Booklet (2019) and in-house written material to structure their consultations. They described highlighting sections of the booklet during their consultations that they regarded as important for the patient and they further described using the headings of sections of the booklet to guide their consultations. This indicated that their consultations were structured around the written material which may have dominated the nurse agenda. The examination of the extent to which Rheumatology Specialist nurses use written material during their consultations with patients has not been researched before. There is little coverage of this topic in any of the extant literature, there is more on the appropriateness of the educational materials for patients and their responses to those materials (Kääriäinen, Kukkurainen et al. 2011, Zangi, Ndosi et al. 2015, Oliffe, Thompson et al. 2019). Thus, is appears in the literature, that there is an emphasis placed on the value of written materials for patients in Rheumatology, there is little evidence around how that information is imparted to the patient by the nurse. This finding from Phase II is an important contribution to the extant literature as it adds a different perspective to be considered when researching this topic.

7.8.2.2 Sub-theme: Overloading Patients with Information

All of the nurses interviewed agreed that they often felt that they were bombarding the patient with information, describing patients as looking shocked or dazed. There has been little research around information overload with Rheumatology patients, but some work has been carried out in the field of Oncology. It has been recognised that many adults feel overwhelmed about the amount of information that they are exposed to which can have an impact on decision-making (Jensen, Pokharel et al. 2020). Jensen et al investigated sun safety behaviour and found that those participants who showed signs of cancer information overload were more likely to not use sun safety behaviour. Ramondt et al (2019) examined the impact of public nutrition information and found that diet information overload resulted in fatalistic beliefs which had a negative impact on preventative behaviours. Thus, the finding of information overload in Phase II is important contribution as it could suggest that

giving too much information to patients may actually have a negative effect. In relation to information giving by nurses in Rheumatology, this finding of information overload, requires more exploration.

7.8.2.3 Sub-theme: Asking Questions

The nurses recognised that patients did not always ask questions during their consultations despite recognising instances where the patient may have wanted to ask questions. However, some literature shows that patients can struggle to ask questions during their consultations (Kinnersley, Edwards et al. 2008) and health literacy may have an impact on this (Menendez, van Hoorn et al. 2017). But it has long been known that encouraging patients to ask questions has a positive impact on satisfaction with their healthcare (Roter 1977) and Shepherd et al (2016) developed three questions for patients to ask during their consultations with healthcare professionals. These three questions encouraged the patients to take part in their consultations and thus supported the shared decision-making process. But the finding from Phase II seems to suggest that the nurses felt "interrupted" by questions from patients rather than encouraging question asking. This important finding does imply that these nurses did not adopt a shared decision-making strategy during their consultations indicating that nurses require training to engage with this technique in order to put patients at the centre of care.

7.8.2.4 Theme Two: Patients have Different Information Needs

It is well recognised that patients need information to help them manage their Rheumatology conditions (Clerehan, Buchbinder et al. 2005, des Bordes, Gonzalez et al. 2018) and factors such as gender (Marrie, Walker et al. 2019) and health literacy (Baker 2006) which can make an impact on individual needs. Thus, the finding from Phase II in which nurses recognised that patients have different information needs, not only adds to this body of knowledge but also suggests that whilst there is awareness of individual information needs, it may not necessarily be explored with the patient. Again, this is

another finding which requires more exploration with a bigger research project to really understand whether healthcare professionals explore different information needs with individual patients and tailor their consultations in order to meet those needs.

7.8.2.5 Theme Three: Time Pressure

Perceived time pressure was a finding from Phase II and it appeared to influence how the nurses conducted their consultations. Time pressure that nurses experience has been well documented in the extant literature, but it is generally related to the pressures of a shortage of nurses and the impact of this on nursing care (Dierckx de Casterlé, Mertens et al. 2020, Labrague, De los Santos et al. 2020) and nurse burnout (Dall'Ora, Ball et al. 2020). There is little in the literature investigating perceived time pressure in nurse consultations but it has been explored for medical consultations (Mazzi, Rimondini et al. 2016) and some GPs report that time pressure is a major barrier to treating disorders such as depression (Hutton and Gunn 2007). From a patient's perspective, they would consider that time matters and if time has been given to resolving issues, it would minimize further visits (Williams and Jones 2006). The nurses' perceptions of time pressure during their consultations and how they manage this is under represented in the literature. Thus, this finding from Phase II is an important contribution to the extant literature, as it emphasizes the need for further exploration of this subject and how nurses manage this through improved consultation technique.

7.8.2.6 Theme Four: Training and Evolution of Practice

There was agreement between all of the participants of Phase II that their practice had evolved over time, and that they did not have specific training to undertake their role of giving information to patients about Methotrexate. This finding strengthens the finding from Phase I which indicated that nurses desired training to carry out their roles more confidently and effectively.

7.8.3 Original Contribution from Phase III

The thematic analysis of the video-recordings and transcripts generated three main themes and their contribution to original knowledge will be described in the following sections.

7.8.3.1 Theme One: The Nurses' Agenda

The findings of the analysis showed that the nurses' agenda of giving information about Methotrexate dominated the consultation which did not put the patient at the centre of care or acknowledge the patient's agenda. However, it did have the benefit of structuring the encounter, ensuring that correct information was given and also provided the patient with written information. Whilst there is little in the literature around this in Rheumatology, a study in cancer nursing confirms that the nurses agenda of giving information dominates and was considered a blocking behaviour resulting in dissatisfaction in cancer patients (Kruijver, Kerkstra et al. 2001). A study by Siouta et al (2019) who audio-recorded nurses in a chemotherapy clinic also showed that the dominant feature of the discourse between the nurse and the patient was the medical and physiological theme. This finding from Phase III, the dominance of the nurses' agenda during their consultation with patients, supports findings from Phase II, information overload and time pressure. It is possible that the nurses agenda dominates because of perceived time pressures and the need to ensure that all of the information from the Methotrexate Information booklet (Versus Arthritis 2019) has been divulged to the patient. It has long been recognised that an improvement in the quality of a consultation can potentially improve aspects of healthcare (Middleton, McKinley et al. 2006). Thus, this is an important finding, because again, it emphasizes that there could be aspects of the Rheumatology nurse consultation which needs further exploration to adapt the consultation technique in order to put the patient at the centre of care, explore the patient's agenda and ensure that the consultation is tailored to the patient's needs.

7.8.3.2 Theme Two: Information Overload

This finding from Phase III supports the finding from the Phase II semi-structured interviews. It is important because it further confirms that Rheumatology Specialist nurses give a lot of information to patients and that they are aware that this is occurring. This finding adds to the body of literature which explores nurse consultations and the implication that there are aspects of these encounters which could benefit from more training.

7.8.3.3 Theme Three: Missed Cues

The data from Phase III revealed this third finding, that opportunities for exploring the patient agenda were missed because these cues were not being recognised or were ignored. The findings from this study have already shown that nurses use written material such as the Methotrexate Information booklet, using the headings in the booklet to guide the discourse they have with the patients during their conversation. This has the effect of dominating the conversation with the patient, it may also result in missing cues from the patient which would indicate that the patient had their own agenda. Whilst the study did not specifically address why the nurses missed these cues, it could have been as a result of perceived time pressure, but there is some evidence which suggests that recognising and dealing with cues focussing on issues important to the patient, could in fact save time (Silverman, Kurtz et al. 2016). Whilst research has been conducted around patient cues (Riley, Weiss et al. 2013, Farrell, Chan et al. 2020) these studies explore verbal cues only. However, they did conclude that nurses were more likely to respond to informational cues than psychosocial cues. The significance of the findings from Phase III is that they add another dimension to the existing knowledge as they reveal that nurses also miss non-verbal cues relating to the patient's agenda.

The adoption of the Medical Interaction Process System to analyse the video-recordings of Phase III permitted the researcher to explore the non-verbal dimension of patient cues which is unique in Rheumatology nursing research. It revealed a variety of verbal and non-verbal items which could indicate whether the consultation between the nurse and patient is effectively addressing patient needs and putting them at the centre of care. Further the

use of the Medical Interaction Process System to analyse the video-recordings showed that it is possible to collect quantitative data giving the opportunity to compare individual nurse consultations. In those consultations which were scored higher, the nurse used more illustrative gestures and it has been seen that the use of illustrative hand gestures improves learning in foreign languages, as it aids recall (Tellier 2010, Macedonia and von Kriegstein 2012, Krönke, Mueller et al. 2013). In the lower scoring consultations the nurses used more batonic gestures, which are those hand gestures which follow a rhythm of speech (Navarretta 2019) rather than illustrate the speech thus it is possible that these types of gestures are not useful to memory recall. This is an important finding because it has not been explored during the nurse patient consultation. It is an area which requires more research as it may indicate that if nurses are taught how to use and gestures to aid recall, it may have a positive impact on the patient experience.

7.8.4 Overall Study Contribution to Original Knowledge

The overarching findings of this study indicate that nurses do not have national gold standard training to conduct their specialist role in Rheumatology, they do not receive training on how to conduct consultations and thus may be missing opportunities to address the patient's agenda putting them at the centre of care and they use written information to guide their consultations which may have the effect of giving patients a lot of information without checking to make sure they have understood what has been said. As a result of these findings, this researcher has collaborated with Versus Arthritis and has produced a sheet of "Top Tips" to guide Rheumatology Specialist nurses during their consultations which was published on the Versus Arthritis website (Versus Arthritis 2020). These "Top Tips" (see Appendix 19) were based on the findings presented in this thesis and are an important education tool for nurses conducting consultations with patients when giving information about Methotrexate. The "Top Tips" are intended to give nurses some guidance around how to give information to patients effectively. The first tip suggests that written information, such as the Methotrexate information booklet, be sent to the patient before they arrive for their consultation with the nurse. This effectively, allows the patient to familiarise themselves with the information first, and come to the consultation with

questions they want to ask. The second tip involves setting the baseline in order to personalise their approach with the patient, to find out what the patient already knows about their treatment and what they want to learn. The third tip is to chunk and check the information the nurse gives to the patient and ascertain how much that person has understood, by asking a question such as "what have you understood about what I have just discussed with you". The fourth tip is to avoid information overload and to emphasise that not every bit of information from the booklet needs to be given. The most important information to give is that around maintaining safety when taking the drug. The fifth tip is to let the patient talk, encouraging the nurse not to dominate the conversation or interrupt, but to legitimise the patient's point of view. The sixth tip is to listen and watch ensuring that the nurse is observing and responding to verbal and non-verbal cues. The seventh tip is to summarise with the patient what has been said during the consultation and the eighth tip is to give the opportunity to the patient to ask question suggesting that the nurse could ask, "what questions do you have?". The final tip is then to give any written information, which could be about the Rheumatology service, blood monitoring appointments and how the patient can get in touch with the team between appointments such as via a helpline. The Top Tips also include a section on the minimum amount of information to give, such as, what to take and how to take it; how long it takes for Methotrexate to work; monitoring requirements; whether changes to the patient's experiences could relate to the drug; potentially serious illnesses and the helpline number to call if the patient needs assistance. These "Top Tips" can be viewed and downloaded by nurses and patients, without charge, via the Versus Arthritis website (Versus Arthritis 2020).

Within the wider context of the specialist nursing role in different disease areas, it is clear that the findings of the three phases of this study support the extant literature that there is a lack of training for many Specialist nurses to develop their roles and consultation skills. Cook et al (2019) comment on the lack of training for Gynaecology Specialist nurses, but consider them important members of the multi-disciplinary team. Dury et al (2014) comment that education programmes are available but there is no regulation or common training frameworks and often the onus of training is on the nurses themselves (Forbes, While et al. 2006).

There is recognition that the role of the Specialist Nurse in Rheumatology has changed and is highly respected as part of the multi-disciplinary team, (Goh, Samanta et al. 2006) but the training around preparing the nurses to meet the demands of this responsibility has not kept pace with the role development (Robinson, Hassell et al. 2017).

7.9 Implications for Education and Practice

The primary purpose of studying the interaction between the nurses and patients during the Methotrexate information process in consultations was to understand that interaction in detail, and to identify any areas where improvement could be made. There are clear messages from this thesis which are summarised in the conspectus, but essentially, nurses were not trained to carry out their role of giving information to patients about Methotrexate and they did not adopt consultation techniques during this process which put the patient at the centre of care; they used written information to guide their consultations which then dominated the nurses agenda; their knowledge of Methotrexate was adequate; they all agreed that specific training would have contributed to their knowledge and confidence in conducting this role.

The research presented in this thesis also raised questions about general nurse education, in that consultation skills are not taught in undergraduate training, but there is a recognition that communication skills are important during the nurse-patient encounter (Nursing and Midwifery Council 2018) and as nurses become more specialised (Royal College of Nursing 2009, Deighan 2011) consultations skills are likely to be of increasing importance to nurses as they take on roles in which they co-ordinate and run outpatient clinics in different specialist areas. It is possible that eventually this training could become part of the general undergraduate training of nurses, but if it is to be postgraduate then it needs to be accessible to busy nurses with limited funding for training; an online package may be appropriate for this. The Calgary Cambridge consultation model that was adopted for the analysis of the video-recorded consultations in Phase III of this thesis seems appropriate to assess the consultation technique of the nurses. It was modified by the researcher, specifically to capture all of the elements which nurses undertake during their consultations.

As Rheumatology Specialist nurses do not regularly carry out physical examinations (other than joint assessments for tenderness and swelling), this domain of the Calgary Cambridge consultation model was removed. The Calgary Cambridge consultation model was deemed to be appropriate for this study, because it had been considered as a model which complements the holistic approach of nurses (Munson and Willcox 2007) and has been adapted by professions other than medicine (Munson and Willcox 2007, Greenhill, Anderson et al. 2011, Englar, Williams et al. 2016). It is a model which helps the nurse to establish a rapport with the patient; give information in chunks and then assess understanding by checking to determine what the patient understood; it allows the patient to be placed at the centre of care and tailor the consultation to individual needs. It also guides the nurse on completing the session with a summary and signposting to further information if required. Thus, this model was specifically adapted by the researcher to focus on the assessment of the nurse consultations. The purpose of the nurse consultation when giving information about Methotrexate is to ensure that the patient understands why they have been prescribed the drug, how to take it safely and how to recognise and report side effects. The patients require individualised consultations tailored to their specific needs, the Calgary Cambridge consultation model provides the structure and flow in order to achieve this. The adapted Calgary Cambridge consultation model could have wider reaching applications. It could provide the basis of all consultations given by nurses, providing them with the skills and guidance to tailor their encounters with patients putting them at the centre of shared decision-making care. However, it is outside of the scope of this thesis but it could provide the basis for future research.

7.10 Limitations

The limitations of each phase have been discussed in the results chapters, but to re-cap, it was not possible to determine whether the responses of the survey were truly representative. Not every participant completed the survey to the end, but the n numbers have been stated to ensure transparency of the results. The survey did not capture geographical data, which may have given the researcher a better representation of the generalisability of the results. However, the survey was sent out by the Royal College of

Nursing (RCN) to all of its members in the Rheumatology forum which has over 1,000 members from all over the UK (RCN 2021), and so whilst some variation is possible, it can reasonably be expected to be geographically representative. Further, it must be acknowledged that the response rate of the electronic survey was typically low, (Monroe and Adams 2012). Despite the extensive use of the electronic survey through the world wide web (www), it has been widely acknowledged that there are challenges to addressing the low response rate (Fan and Yan 2010). The survey described in this thesis was distributed via the RCN Rheumatology forum via an email link. This could have compromised the response rate, as spamming filters are increasingly being used to cut down on unnecessary www email traffic in to organisations (Daikeler, Bošnjak et al. 2020). Some authors also believe that participants are becoming increasing resistant to responding to surveys in general (Kohut, Keeter et al. 2012). Further, web surveys are often overlooked because they are not mandatory and it is easier to put them aside as opposed to having personal contact with the participant by the researcher making more difficult to refuse to participate (Dillman, Smyth et al. 2014). Incentives are strategies employed by some researchers to increase response rates (Monroe and Adams 2012), however, this particular strategy was not available to this researcher. Hendra and Hill (2019) explain that some surveys can cost large amounts of money, therefore they explored the response rate of sixteen identical surveys, which included 12,000 participants and concluded that the pursuit of high response rates may offer little or no reduction of nonresponse bias, that samples with higher response rates had levels of nonresponse bias which were similar to those studies which had a lower response rate, thus costly incentives may be unnecessary.

The interviewees from Phase II came from two different units with dissimilar appointment structures for the interaction with patients for giving information about Methotrexate and the nurses from one of the units had the opportunity to engage in a specific Rheumatology course run by a Nurse Consultant in their department, at their local university. However, the analysis of resulting interviews showed little difference in the way that the nurses gave information to patients, the same themes emerged and the same lack of basic training was apparent.

Whilst the video-recordings yielded a lot of data, all of the recordings came from one Rheumatology service. Whilst the findings cannot be considered as necessarily

generalisable, the findings from Phase I and II demonstrated the same links and patterns, in that nurses generally did not receive training, they used written information to guide their consultations and they felt that structured training would have given them more confidence to carry out their role. So, whilst this is a small study, the findings from this work adds to the extant literature as this is a unique study in Rheumatology nursing and enriches our understanding of how nurses are trained to conduct their role as Methotrexate information givers to patients, and also how they conduct their consultations. It has also highlighted that consultation techniques are important skills which allowed the nurses to recognise cues, tailor their consultations to individual patients and to put the patient at the centre of their care in shared decision-making.

7.11 Further Recommendations

This researcher has recognised that the findings from this study shows that nurses use written information during their consultations consistently and that this information ensures that the nurse gives the pertinent information to the patient. However, the written information usually takes the form of the Versus Arthritis booklet on Methotrexate which was designed and written for patients (Versus Arthritis 2019) and it dominates the nurse's agenda leaving little opportunity for patients to interact during this process. This booklet contains information that patients need but it does not have the depth of information required by nurses to carry out their role. It also has no guide around conducting the consultation, ensuring that patients understand the information they are being given and are part of the shared decision-making process leading to greater self-management (Elwyn, Frosch et al. 2012, El Miedany, El Gaafary et al. 2016, Mathijssen, Vriezekolk et al. 2020). Further, the influences of consumerism in the NHS (Latimer, Roscamp et al. 2017) and the rights of the patients to be involved in their care and decision-making processes (Sykes and Durham 2014) should be reflected in the way that nurses conduct their consultations when giving information to patients about Methotrexate. Whilst in some cases there may be resource limits to patients choices which are unavoidable (Latimer, Roscamp et al. 2017), it should still be a priority to nurses to ensure that patients understand the choices available to them, ensuring that drug treatments such as Methotrexate are explained and understood

by patients so that they are placed at the centre of their care. Therefore, this researcher is now designing a study to develop a nurse handbook, containing background information about Methotrexate and guidance on how to conduct a consultation by applying an adaptation of the Calgary Cambridge consultation model. This will provide information for nurses to develop the skills to ensure that nurses tailor their consultations to suit the individual needs of their patients, thus streamlining their interaction so that only the pertinent information is given. The aim of this would be to ensure that nurses have a greater depth of information about the drug they are explaining to the patient, have the skills to ensure that patients are at the centre of care and to be able to use the time allocated to conduct their consultations in an efficient way. Further the booklet will offer tips, based on the "Top Tips" to increase the effectiveness of their interactions which could suggest sending the patients the written information about Methotrexate prior to their appointment with the nurse, which will give patients time to read the material and have any queries or concerns ready, prior to the consultation. This will then allow the nurses to concentrate on patients concerns ensuring that issues which are important are explored thus resulting in a consultation which focusses on individual needs for information and guidance. The handbook will also advise on time efficiency so that the nurse will feel less constrained by time perceptions and allows them to involve the patient more during the consultation without necessarily prolonging the interaction. The handbook will also be designed to guide nurses on the importance of patient cues and how to interpret verbal and non-verbal behaviours. Further possible research could also investigate whether the use of the handbook results in behaviour change; whether other factors such as cultural and belief systems could impact on the use of the handbook and whether the handbook saves time during the consultation which could result in patients asking more questions. Investigations such as these, could be tested with further research.

On a larger scale, a national training package to ensure that nurses have gold standard training for carrying out these roles would ensure that every nurse had the skills and training required to underpin their role. It would need to include consultation skills, such as adapting the Calgary Cambridge consultation model to suit the nurse's role and a greater level of drug information about drugs such as Methotrexate. The Calgary Cambridge consultation model was adapted by the researcher to analyse Phase III of the work

presented in this thesis. The adaptations involved removing those domains of the Calgary Cambridge consultation model which did not apply to the nurse consultation, such as physical examination and diagnosis. However, the emphasis of the model is to provide information to the patient in manageable chunks and check understanding through the patient's response. Thus, the elements which were retained were; initiating the consultation, setting the agenda, checking the patient's current knowledge/information, understanding the patients concerns, giving explanations and information by chunking and checking, supporting with written information and closing the consultation with summarising and an agreed plan. This adapted model gives structure to the nurse consultation, provides clarity and flow putting the patient at the centre of care.

Whilst this study concentrated on nurses giving information to patients about Methotrexate, there are many more drugs which are discussed by nurses with patients during their treatment. A training package should include all of the commonest drugs which nurses encounter in the information giving process. This is particularly important when giving information about drugs which have significant side effects and require the patient to recognise and report these in a timely manner. A number of drug companies have attempted to provide on-line training resources for Rheumatology Specialist nurses regarding different aspects of their role, (Eli Lilly 2021) however, these are not standardised or regulated and therefore have limitations. Whilst the Royal College of Nursing has produced excellent competencies for Rheumatology Specialist nurses (Royal College of Nursing 2020) which was supported by AbbVie Pharmaceuticals Ltd (Finney, Parker et al. 2020), achieving these competencies still require training. Therefore, an online training resource based on those competencies and regulated by a recognised organisation such as the British Society of Rheumatology or the Nursing and Midwifery Council, could be a more appropriate way forward. However, the development of this is outside the scope of this thesis but it may be embraced in future research.

7.12 Conclusion

Previous studies (Sowden, Hassan et al. 2012, Walker, Robinson et al. 2012, Fayet, Savel et al. 2016) recommended that deficiencies in core knowledge of patients needed to be addressed. Rheumatology Specialist nurses largely take on this role of giving information to patients about Methotrexate when they start this drug but little was known about how they are trained to carry out this role in a consultation (Royal College of Nursing 2009). Thus, the findings of the research described in this thesis supports the viewpoint that structured gold standard training for nurses will improve confidence in conducting their role.

This thesis has demonstrated the processes that nurses adopted in order to give information to patients about Methotrexate in their consultations. It showed that nurses used information leaflets to guide their consultations, and that this dominated the nurses' agenda, thus reducing opportunities to implement a shared-decision-making process between the nurse and patient, and it also provided few openings for patients to express their concerns. The domination of the nurses' agenda also resulted in missing cues from the patients which may have impacted on the patient experience of the interaction with the nurses. This thesis also showed that nurses want more training and they recognised that it would lead to feeling more confident to conduct their roles. Further, the utilisation of the Calgary Cambridge consultation model could provide the framework with which nurses could structure their interaction with patients thus facilitating the patient agenda. This thesis has contributed to the extant literature on how nurses give information to patients about Methotrexate and it employed an analysis method, the Medical Interaction Process System, which was unique in this area of research. The findings of this research have been published in three manuscripts, which can be seen in appendices 20, 21 and 22, and a fourth manuscript is currently being prepared.

This researcher is now embarking on a further research project as a result of the findings of this work, highlighting the importance of consultation skills and conveying information to educate patients as identified in this thesis. As described in the previous section, this researcher will develop a handbook for nurses to guide them on their consultation technique. It is envisaged that the first section of the handbook will describe the consultation process based on the Calgary Cambridge consultation model, this will give step

by step guidance on how to conduct this consultation, to support the nurse to tailor the discussion around the patient agenda. The second section of the handbook will give the nurse more information about the drug they are discussing with the patient and the minimal amount of information the patient needs to ensure they understand why they are taking the drug, that they can take their treatment safely and recognise side effects which need to be reported early. Once the handbook has been developed, it will be validated for effectiveness through a research study and amended based on the findings of that study. It has already been highlighted that the lack of training for nurses in specialist roles occurs in other specialities, thus it is possible, that if the handbook is successful in Rheumatology, that there may be opportunities for adaptation and use in other specialist areas.

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Appendices

Appendix 1 Parliamentary Debates around the use of Cortisone 1949 – 1954

Between 1949 and 1954 a series of debates around the availability of Cortisone was brought up in Parliament:

Colonel J.R. Hutchison asked the Minister of Health what steps he was taking to encourage the production of the anti-arthritis discovery Cortisone, to which Mr Bevan replied:

> "The Medical Research Council……is promoting intensive research into Cortisone and other substances that might take its place and be available in adequate amounts" (Hansard 1949).

In 1950 it was reported that Cortisone was readily available in America, Mr Blackburn a Conservative MP remarked:

> "Is it a fact that, as reported, Cortisone is being made available at drug stores in the United States next month?" (Hansard 1950).

However, in 1951, Cortisone was still not available in the UK, even though it was being manufactured in America, as commented by Mr Crookshank, Minister for Health (1951 – 1952);

> "Cortisone has not yet been made in this country. The maximum quantities which can be made available by the American manufacturers are imported by my Department and distributed for continuing clinical research and for hospital treatment for cases which, on medical grounds, most need it." (Hansard 1951).

The "period of scarcity" ended in 1952 when Murray and Peterson who worked for an American Pharmaceutical Company call Upjohn (Hetenyi Jr and Karsh 1997), discovered that a mould was discovered called Rhixopus Nigirans, converted progesterone into cortisone with an almost 100% yield. It was now possible to produce cortisone in large quantities and

in 1953 Upjohn produced and marketed hydrocortisone, but there was still caution around its use in the UK as commented by Iain Macleod Conservative MP:

> "I must say that on the whole I prefer in these matters to proceed rather cautiously. For all the claims that are made about Cortisone there are very considerable unknown dangers in it". (Hansard 1953).

By 1954 Cortisone was becoming more available, but there was still caution in the air as Iain Macleod comments;

> "We are at the moment limiting the distribution of Cortisone – the supply position is rapidly becoming a great deal easier – to about 100 hospitals. It is hoped to extend the distribution very considerably. However, the use of the drug must, clearly, be entirely at the discretion of the doctors. One obviously cannot deny Cortisone to a patient if it is thought desirable that he should have it…." (Hansard 1954).

Despite the advance in the treatment of RA brought about through increased availability of hydrocortisone, treatment effects did not meet the expectations of the 1950s. Hart (1976, p763-765) wrote,

> "The treatment of an untreatable condition such as Rheumatoid Arthritis calls forth, as they might well say in Tipperary, great therapeutic skill and expertise".

Appendix 2 Annexe A

1. Underpinning communication skills for assessing, planning, providing and managing best practice, evidence-based nursing care

1. Actively listen, recognise and respond to verbal and non-verbal cues.
2. Use prompts and positive verbal and non-verbal reinforcement, eye contact and personal space.
3. Make appropriate use of open and closed questioning.
4. Use caring conversation techniques.
5. Check understanding and use clarification techniques.
6. Be aware of own unconscious bias in communication encounters.
7. Write accurate, clear, legible records and documentation.
8. Confidently and clearly present and share verbal and written reports with individuals and groups.
9. Analyse and clearly record and share digital information and data.
10. Provide clear verbal, digital or written information and instructions when delegating or handing over responsibility for care.
11. Recognise the need for, and facilitate access to, translator services and materials.

2. Evidence-based, best practice approaches to communication for supporting people of all ages, their families and carers in preventing ill health and in managing their care

1. Share information and check understanding about the causes, implications and treatment of arrange of common health conditions including anxiety, depression, memory loss, diabetes, dementia, respiratory disease, cardiac disease, neurological disease, cancer, skin problems, immune deficiencies, psychosis, stroke and arthritis.
2. Use clear language and appropriate written materials, making reasonable adjustments where appropriate in order to optimise people's understanding of what has caused their health condition and the implications of their care and treatment.
3. Recognise and accommodate sensory impairments during all communications.

4. Support and manage the use of personal communication aides.
5. Identify the need for and manage a range of alternative communication techniques.
6. Use repetitive and positive reinforcement strategies.
7. Assess motivation and capacity for behaviour change and clearly explain cause and effect relationships related to common health risk behaviours including smoking, obesity, sexual practice, alcohol and substance use.
8. Provide information and explanation to people, families and carers and respond to questions about their treatment and care and possible ways of preventing ill health to enhance understanding.
9. Engage in difficult conversations, including breaking bad news and support people who are feeling emotionally or physically vulnerable or in distress, conveying compassion and sensitivity.

3. Evidence-based, best practice communication skills and approaches for providing therapeutic interventions

1. Motivational interview techniques.
2. Solution focussed therapies.
3. Reminiscence therapies.
4. Talking therapies.
5. De-escalation strategies and techniques.
6. Cognitive behavioural therapy techniques.
7. Play therapy.
8. Distraction and diversion strategies.
9. Positive behaviour support approaches.

4. Evidence-based, best practice communication skills and approaches for working with people in professional teams

1. Demonstrate effective supervision, teaching and performance appraisal through the use of:

- Clear instructions and explanations when supervising, teaching or appraising others
- Clear instructions and check understanding when delegating care responsibilities to others
- Unambiguous, constructive feedback about strengths and weaknesses and potential for improvement
- Encouragement to colleagues that helps them to reflect on their practice
- Unambiguous records of performance

2. Demonstrate effective person and team management through the use of:
    - Strengths based approaches to developing teams and managing change
    - Active listening when dealing with team members' concerns and anxieties
    - A calm presence when dealing with conflict
    - Appropriate and effective confrontation strategies
    - De-escalation strategies and techniques when dealing with conflict
    - Effective co-ordination and navigation skills through:
        - appropriate negotiation strategies
        - appropriate escalation procedures
        - appropriate approaches to advocacy

Appendix 3 Methotrexate Information Booklet

Drug information

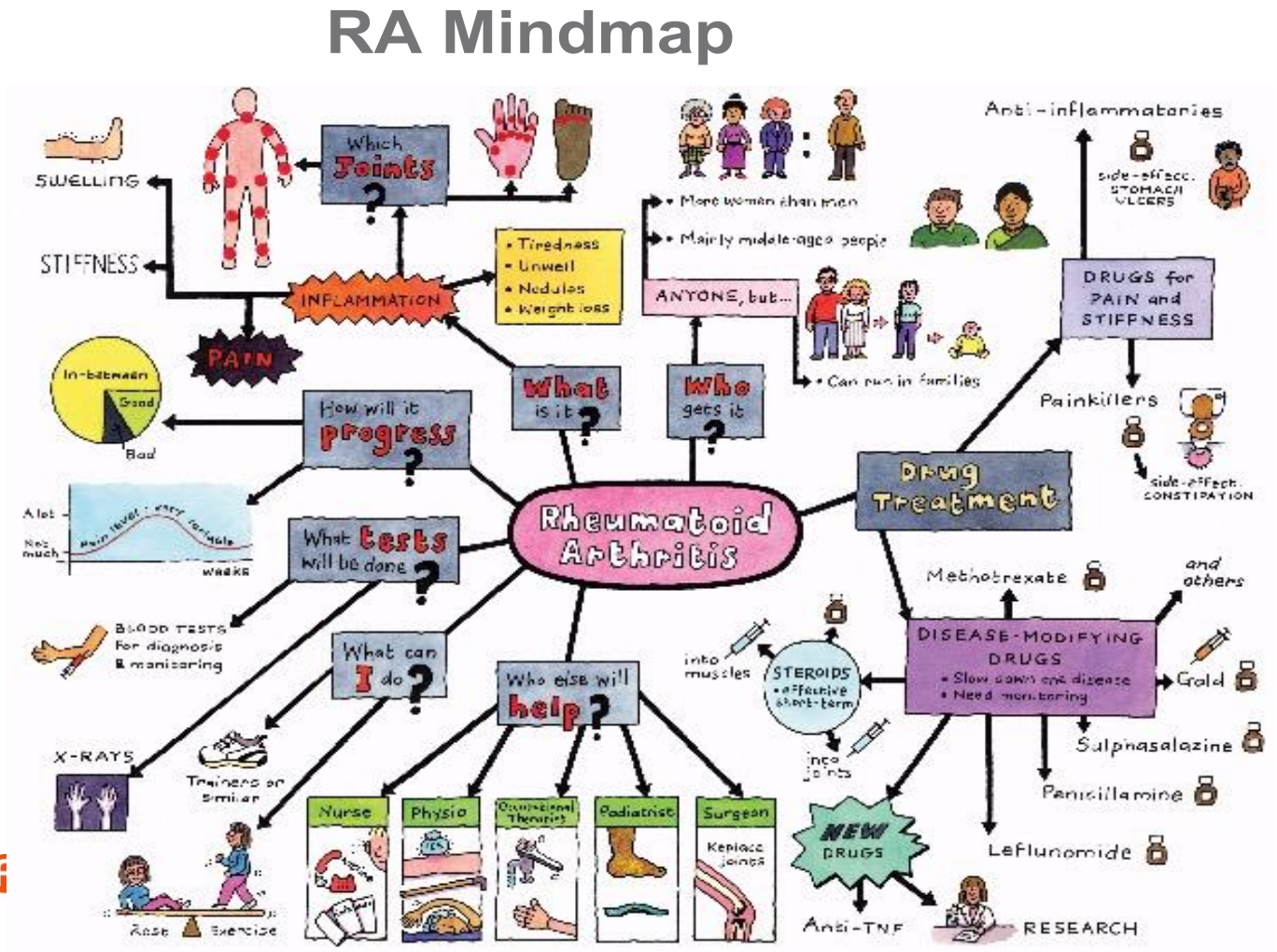
Methotrexate

METHOTREXATE

is used to treat a number of conditions, including rheumatoid arthritis, psoriatic arthritis, vasculitis and juvenile idiopathic arthritis

VERSUS ARTHRITIS

Appendix 4 Rheumatoid Arthritis Mindmap



Appendix 5 The REALM

REALM Health Literacy Test
(Rapid Estimate of Adult Literacy in Medicine)

How many of these words can you read aloud and pronounce correctly, each within five seconds? Start with the first column, reading down. Skip those you cannot read.

Fat	Fatigue	Allergic
Flu	Pelvic	Menstrual
Pill	Jaundice	Testicle
Dose	Infection	Colitis
Eye	Exercise	Emergency
Stress	Behavior	Medication
Smear	Prescription	Occupation
Nerves	Notify	Sexually
Germs	Gallbladder	Alcoholism
Meals	Calories	Irritation
Disease	Depression	Constipation
Cancer	Miscarriage	Gonorrhea
Caffeine	Pregnancy	Inflammatory
Attack	Arthritis	Diabetes
Kidney	Nutrition	Hepatitis
Hormones	Menopause	Antibiotics
Herpes	Appendix	Diagnosis
Seizure	Abnormal	Potassium
Bowel	Syphilis	Anemia
Asthma	Hemorrhoids	Obesity
Rectal	Nausea	Osteoporosis
Incest	Directed	Impetigo

SCORE

Add up the number of words pronounced correctly.

0—18 words ***Third grade or below*** You will not be able to read easy materials. You will need repeated oral instructions, materials composed primarily of illustrations, or audio or videotapes,

19—44 words ***Fourth to sixth grade*** You will need easy materials. You will not be able to read prescription labels.

45—60 words ***Seventh to eighth grade*** You will struggle with most patient education materials and will not be offended by low-literacy materials.

61—66 words ***High school*** You will be able to read most patient-education materials

Source: Rapid Estimate.of Adult Literacy in Medicine
The New York Times

Appendix 6 COREQ 32 item checklist for reporting qualitative studies

Domain 1: Research team and reflexivity	
Personal characteristics	
1. Interviewer/facilitator	Which author/s conducted the interview/focus group? ***The researcher conducted all of the interviews.***
2. Credentials	What were the researcher's credentials? ***The researcher was a qualified nurse with 15 years' experience in research and had previous experience with semi-structured interviews.***
3. Occupation	What was their occupation at the time? ***Senior Nurse Researcher***
4. Gender	Was the researcher male or female? ***Female***
5. Experience and training	What experience/training did the researcher have? ***Completed Good Clinical Practice training, over 15 years' experience in academic research.***
Relationship with participants	
6. Relationship established	Was this established prior to the study? ***The researcher had the opportunity to meet all of the participants before the interviews, to talk about the project and their participation.***
7. Interviewer known to participant	Did the participant know the researcher? ***The participants had met the researcher previously and was known to them.***
8. Interviewer characteristics	What characteristics were reported eg biases, assumptions. ***The participant characteristics were reported as some nurses had been carrying out the role for longer than others.***
Domain 2: study design	
Theoretical framework	
9. Methodological Orientation And Theory	What Methodology underpinned the study? ***A phenomenological methodology underpinned the semi-***

	structured interviews as it seeks to explore lived experiences.
Participant selection	
10. Sampling	How were participants selected? ***Purposive sampling was applied and nurses from 2 Rheumatology centres were invited to take part in the study. 3 nurses from each centre consented to be interviewed.***
11. Method of approach	How were participants approached? ***All of the nurses were approached, to ensure that 6 individual nurses could be interviewed.***
12. Sample Size	How many participants were there? ***6 nurses agreed to be interviewed.***
13. Non participation	How many participants refused/dropped out and why? ***No nurses dropped out, but the reason given for refusal to take part was that the nurse did not have time, or did not want to be interviewed.***
Setting	
14.Setting of data collection	Where was the data collected? ***The interviews took place in a quiet, undisturbed office space in each Rheumatology Unit.***
15. Presence of non-participants	Was anyone else present? ***Only the interviewer and the interviewee were present during the interaction.***
16. Description of sample	What are the important characteristics of the sample? ***All of the nurses were qualified as Registered Nurses, all of the nurses gave information to patients about Methotrexate.***
Data collection	
17. Interview Guide	Were questions/prompts/guides provided – was it pilot tested? ***The interview guide was developed by the researcher and it was then reviewed by peers and the researcher's supervisors.***
18. Repeat Interviews	Were interviews repeated, if so how many? ***No interviews were repeated.***
19. Audio/visual recording	Was audio/visual recording used to collect data?

	All of the interviews were recorded on a Dictaphone.
20. Field notes	Were field notes made? ***Notes were made by the researcher and documented anything which could have impacted on the quality of the interviews such as her rapport with the interviewees, the comfort of the space in which the interviews took place, whether the interviewee was nervous or limited for time.***
21. Duration	How long was the interview/focus group? ***Each interview took approximately 30 minutes.***
22. Data saturation	Was data saturation discussed? ***Data saturation was discussed with the researcher's supervisor.***
23. Transcripts returned	Were transcripts given to participants for review? ***All transcripts were given back to the interviewees to check accuracy and ensure they did not want to add anything they may have missed.***
Domain 3: analysis and findings	
Data analysis	
2 4. Data coders	How many data coders were there? ***2 data coders coded the same transcript to determine inter-rater reliability. Thereafter, the researcher coded the transcripts.***
25. Description of coding	Is there a description of the coding tree? ***Notes were taken of the processes undertaken to examine the transcripts for emerging themes.***
26. Derivation of themes	Were themes identified in advance or derived from the data? ***All themes were derived from the data.***
27. Software	What, if any, software was used? ***A software package was not used.***
28. Participant checking	Did participants provide feedback? ***The only feedback given by the participants was that they consented for the transcripts to be used.***
29. Quotations presented	Were quotes used to illustrate themes/findings and were they identified? ***Quotes were used to illustrate themes and were identified by an***

	anonymised participant number.
30. Data/findings consistent	Was there consistency between the data presented and the findings? ***There was consistency between the data presented and the findings.***
31. Clarity of major themes	Were major themes clearly presented? ***All major themes were clearly presented.***
32. Clarity of minor themes	Is there a discussion/description of minor themes? ***Minor themes emerging from the major themes were also identified.***

Appendix 7 The Methotrexate Nurse Training Questionnaire

1. Do you advise/educate patients with respect to starting Methotrexate treatment?

Yes □ No □

2. How many patients on average do you advise/educate per week?

1-4 ☐

5-9 ☐

10-15 ☐

Over 15 ☐

3. How long have you been doing this?

0-6 months ☐

6-12 months ☐

1-5 years ☐

Over 5 years ☐

4. Would you describe yourself as a Rheumatology nurse specialist?

Yes □ No □

If NO what is your role?

_____

_____

_____

If YES how many years have you worked in Rheumatology?

_____

_____

_____

5. What year did you qualify?

_____

_____

_____

6. Did you have any training before you took on the role of Methotrexate adviser? (Please circle your answer)

No training □ Some training □ A lot of training □

Please describe any training you had:

_____

_____

_____

_____

_____

7. If you had training, how helpful was it?
(Please circle your answer)

No help □ Some help □ Moderately helpful □ Very helpful □

8. Would you have liked more training? YES NO
Yes □ No □

If YES what kind of training would you have liked?

_____

_____

_____

_____

9. How confident are you at educating and advising patients on Methotrexate?

Not at all confident	Somewhat confident	Confident	Very confident
□	□	□	□

10. Has the way you advise patients changed from when you started?

A lot □ In some ways □ Not at all □

Please describe:

_____

_____

_____

_____

11. How long did it take you to become confident at advising patients about Methotrexate?

0-2 months ☐

2-6 months ☐

☐

6-12 months

Over 1 year ☐

12. What training do you think nurses need to educate patients about Methotrexate?

Communication skills:

None □ A little □ Some □ A lot □

Consultation skills:

None □ A little □ Some □ A lot □

Knowledge:

None □ A little □ Some □ A lot □

Experience:

None □ A little □ Some □ A lot □

Other_____

_____

_____

_____

13. What written information do you use when educating patients about Methotrexate? (please tick all that apply)

□ In house information leaflet
□ ARUK leaflet
□ NRAS
□ Other, please state below

_____

_____

_____

_____

14. How useful is the written information you use?

Not useful □ A little useful □ Quite useful □ Very useful □

15. Methotrexate is used to treat which of the following conditions? (There may be more than one answer, please tick all that apply)

□ Osteomalacia
□ Rheumatoid Arthritis
□ Psoriatic Arthritis
□ Vasculitis

16. A 61 year old man with RA for 7 years is going on holiday. He normally takes Methotrexate 20 mg weekly, folic acid 5 mg weekly, and atenolol 50mg daily for hypertension. Which of the following vaccinations should this patient NOT have?

□ Flu Vaccination
□ Tetanus
□ Yellow Fever
□ All of the above

17. A 45 year old lady with RA for 7 years arrives at clinic complaining that she has been very breathless for the last couple of days. She has been taking her treatment as usual which comprises Methotrexate 15mg weekly, folic acid 5mg weekly, sulfasalazine 2g daily, and cocodamol prn. Do you:

□ Tell her to go to her GP as you suspect a chest infection
□ Tell her to increase her Folic Acid
□ Stop the drug and refer to a Rheumatologist
□ Tell her not to worry as this is normal whilst on Methotrexate

18. A 72 year old lady with RA for 22 years is normally treated with Methotrexate 20mg weekly, folic acid 5mg daily, ramipril 2.5mg daily and atorvastatin. She is about to start antibiotics for cellulitis. Which of the following antibiotics should she avoid?

□ Amoxycillin
□ Erythromycin
□ Flucloxacillin
□ Trimethoprim

19. A 76 year old lady with RA for 15 years, normally treated with Methotrexate 20mg weekly, folic acid 5mg daily, bendroflumethiazide 2.5mg daily and atorvastatin, has suspected pyelonephritis and is to start treatment with Kefalexin. What advice would you give regarding the Methotrexate?

□ Carry on taking the Methotrexate but to drink more water
□ Reduce the dose of Methotrexate until the infection has cleared
□ Increase the dose of folic acid
□ Stop the Methotrexate until the infection has cleared

20. A previously fit 60 year old man with recently diagnosed RA is to start combination treatment with Methotrexate and hydroxychloroquine. He asks you whether he can continue to drink alcohol when he commences Methotrexate. Do you advise him:

□ That it is safe to drink alcohol
□ That he should not drink any alcohol
□ To keep to the governments recommended amount of 21 units a week
□ To limit his alcohol intake to no more than 4 units a week

21. A 25 year old woman has a 3 year history of RA treated with Methotrexate 15mg weekly, sulfasalazine 2g daily and folic acid 5mg weekly. She and her partner wish to try for a family. For how long should the patient stop Methotrexate before attempting to conceive?

□ 2 weeks
□ 2 months
□ 3 months
□ 6 months

22. A 30 year old man with RA for 6 years, treated with Methotrexate 20mg weekly and weekly folic acid, mentions he and his partner have decide to start a family. He asks whether there is any advice with respect to taking his Methotrexate while they try to conceive. What do you advise?

□ No specific action regarding his treatment is required
□ He should stop the Methotrexate for 2 weeks prior to them trying to conceive
□ He should stop the Methotrexate for 2 months prior to them trying to conceive
□ He should stop the Methotrexate for 3 months prior to them trying to conceive
□ He should stop the Methotrexate for 6 months prior to them trying to conceive

23. A 36 year old woman has had Rheumatoid Arthritis for 5 years. She is currently treated with oral Prednisolone 5mg/day; Methotrexate 20mg/week; Sulfasalazine 2 g/day and Folic Acid 5mg/week. She attends your monitoring clinic concerned that she has been told by her GP that she has shingles affecting her left upper limb. State whether each of the following statements is true or false.

a) Anyone can catch shingles from an infected person — **True False**

b) People are at risk of developing chicken pox from contact with a person who has shingles. — **True False**

c) A person with a past history of chicken pox is unlikely to catch shingles from an infected person — **True False**

d) Shingles can be more severe in patients taking Methotrexate and Steroids — **True False**

5. Chicken Pox can be more severe in patients taking Methotrexate and Steroids — **True False**

24. A 56 year old man with a 10 year history of Rheumatoid Arthritis attends the monitoring clinic. He is taking Methotrexate 15mg/week sc; Folic Acid 5mg 6 days/week; Hydroxychloroquine sulphate 200mg/day, Naproxen 250mg qds and Atenolol 50mg/day. His blood tests for the last 3 months are shown below:

	Hb 13-18	WCC 4-11	Plat 150-400	MCV 80-96	ALT 5-35	APhos 45-105	Bilirubin 1-22	Alb 37-49	ESR 0-20
June 1st	13.2	5.4	212	85	56	46	21	35	25
July 1st	12.9	5.8	256	87	85	50	14	39	28
Aug 1st	13.0	5.2	220	84	140	96	17	34	30

Which drug is most likely to be a cause of the abnormality which has developed in the patient's results?

1. Methotrexate
2. Hydroxychloroquine
3. Naproxen
4. Atenolol
5. Folic Acid

25. A 56 year old man with a 10 year history of Rheumatoid Arthritis attends the monitoring clinic. He is taking Methotrexate 15mg/week sc; Folic Acid 5mg 6 days/week; Hydroxychloroquine sulphate 200mg/day, Naproxen 250mg qds and Atenolol 50mg/day. His blood tests for the last 3 months are shown below:

	Hb 13-18	WCC 4-11	Plat 150-400	MCV 80-96	ALT 5-35	APhos 45-105	Bilirubin 1-22	Alb 37-49	ESR 0-20
June 1st	13.2	5.4	212	82	35	15	21	36	25
July 1st	11.9	5.8	350	70	45	36	14	39	28
Aug 1st	10.0	5.2	436	65	37	42	17	37	30

Which drug is most likely to be a cause of the abnormality which has developed in the patient's results?

1. Methotrexate
2. Hydroxychloroquine
3. Naproxen
4. Atenolol
5. Folic Acid

26. A 76 year old woman with longstanding Rheumatoid Arthritis attends clinic. Her treatment comprises Methotrexate 10mg/week; Folic Acid 5mg/week; Simvastatin 40mg/day and Ramipril 5mg/day.
Urine dipstick testing show:

Leucocytes	Protein	Nitrites	Glucose
++	Trace	Positive	Negative

What course of action would you take?

1. Arrange an MSU
2. Stop Methotrexate
3. Start Amoxicillin
4. Refer to the patient's GP
5. Refer to the Rheumatologist

27. Do you have any other comments?

Appendix 8 Ethics Approval for Phase I and Phase II

NRES Committee North East - Sunderland
Room 002
TEDCO Business Centre
Viking Business Park
Jarrow
Tyne & Wear
NE32 3DT

Telephone: 0191 4283563
Facsimile: 0191 4283432

12 March 2013

Dr David Walker
Consultant Rheumatologist
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Musculoskeletal Directorate,
Freeman Hospital
Newcastle Upon Tyne
NE7 7DN

Dear Dr Walker

Study title:	**A study of the learning needs of nurses educating patients starting Methotrexate.**
REC reference:	**13/NE/0092**
IRAS project ID:	**111845**

Thank you for submitting revised documentation, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by myself as Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Helen M Wilson, nrescommittee.northeast-sunderland@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Appendix 9 Northumbria Healthcare NHS Foundation Trust R&D Approval for Phase I and Phase II

Northumbria Healthcare NHS
NHS Foundation Trust

Research Support Unit

Prof Richard Walker ***Direct Line:*** ***0191 293 2709***
Director of Research & Development ***Fax:*** ***0191 293 2709***

Research and Development Office Direct dial 0191 2934087 or Tel: 0844 811 8111

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Liz Costigan	*Admin Assistant*	*Liz.costigan@nhct.nhs.uk*	*Ex 2829*

15 April 2013

Dr David Walker
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake lane
North Shields
NE29 8NH

Dear Dr Walker

Re: Nurse learning needs of patients starting Methotrexate

CSP Ref: 111845

I confirm that I am happy to give approval and provide indemnity for the above study to take place within this Trust.

Please note that it is a condition of this agreement that the Research Support Unit ***must*** be notified of:

- Any significant changes to the study design.
- Commencement and completion of the study.
- Any decision made by a Research Ethics Committee regarding this study.
- Any adverse effects upon subjects.
- Any suspension or abandonment of the study.
- All funding, awards and grants pertaining to this study, whether commercial or non-commercial.
- All final reports, publications and/or conference presentations of the findings of the study.

Commencement of any work related to this study, using Trust resources or premises, implies agreement with the above conditions.

Yours sincerely

Mr Jim Mackey
Chief Executive

In association with the University of Newcastle upon Tyne

LP30255

Appendix 10 Nurse Responses to the Way Nurses Change the Way They Give Information to Patients over Time

in the language used in a consultation and tailoring to the pt needs

The drug therapy is now licensed and storage in a fridge is no longer required.

Long shelf life Patients encouraged to administer their own injections. Previously had a set Methotrexate clinic.

you gain experience through other patient's experiences and that enhances you knowledge and can enhance your education of the drug and leads to an enhanced counselling for the patient

I use the purple Methotrexate booklet to guide most of the patient education.

Then supplement this with facts about efficacy and risks as i have gained more education.

I have also used examples reported by patients and am developing a visual aid to demonstrate safety for patients who are unsure about commencing treatment based upon research papers looking at the safety profile of MTX

More knowledgeable in pharmacology of MTX, side effects, monitoring and results. More confident in dealing with 'non-compliant' patient.

With experience come confidence

give short bursts of information each visit rather than trying to cover everything in one go

Patient empowerment therapies Educational /communication initiatives to improve compliance

after my own research and observing other practice i have gained in knowledge and in confidence.

I was initially not confident at all, but over the years my knowledge and experience has grown which has changed the way I feel.

Guidelines change so need to keep up to date. My confidence in the information I deliver Initially, I was constantly referring to the RCN guidelines.

I only see these patients in a small capacity as part of a more generalized role. I would say less than 6 per year

The way we use MTX now is different re dose increases being 5mg instead of 2.5mg

I am more aware of risks associated with MTX and use the NPSA booklet with every prescription, ensuring the patient reads it though fully before they start. We also have a stamp that we use in the notes to list discussion around fertility, side effects, consent, monitoring etc.

MORE KNOWLEDGEABLE AND CONFIDENT IN EDUCATING PATIENTS

Use a lot more s/c Methotrexate now, also monitoring guidelines etc have changed

Patients need to be educated about their disease first before MTX. Through this one provides the patient with a sound rationale for taking MTX.

If they are convinced of the need patients will take on board the information more carefully.

Yes. Patients are more likely to come to clinic armed with questions so its not just about talking to patients but about answering their concerns

Written information provided to patients has changed Blood test frequency reduced. Changes to advice given alters as latest research is produced

e.g. Side effect profile

I repeat important messages. I don't use written prompts anymore. I feel more confident to answer any questions that arise

Because I have experience of using MTX and know that it is a good drug I feel that I sell it better!

The more experience I get the more confident I become. Also, completing the non-medical prescribing course a few years ago forced me to look further into the pharmacology aspect of Methotrexate.

We now keep clear checklist records which are signed as a record of exactly what information we gave to the patient, and what their blood tests

and chest x-ray results were at the time of starting. I guess careful documentation becomes more and more important over time.

Changed with experience and became more confident, not what needed to be said but perhaps the delivery of the information. Having done it a few times I can adapt what I say more to the individual

a lot more structure We have a proforma to follow as to what education all pt have to have had

More relaxed. Emphasize the positive. More familiar with tx

Give information in stages. Check at each visit that the patient has remembered what has been said

I have changed my practice in some ways through learning from experience. If it works well with 1 patient, adapt and develop. Also useful to use articles from NRAS news as well as ARUK leaflets.

Able to signpost patients where they can gain more information i.e. arthritis helplines or talking to another patient who is already taking it.

From a dedicated session for counselling - 1 hour, now put into "normal" clinic for 30 mins only, as we are shunted into private health care this may reduce even further as our workloads are increased but time allowed isn't. With greater understanding and data available on the disease process and drug itself i have updated my education use the AR UK leaflets to go through, introduced packs with everything in needed for the patients to start Methotrexate.

more flexible in my approach - able to work with the patients agenda rather than my own.

Able to discuss in depth the details required by the patient and I am aware of up to date research and guidance to enable the patient to make an informed choice regarding their care. Consistent in the quality of information given now. Improved records of education sessions in patient notes.

From when I started in Rheumatology 20years ago much has changed !!!, including the use of Methotrexate and education.

Knowing much more about history taking, diagnosis and it's importance per se; about the conditions such as RA, PsA etc ; the rationale for use of Methotrexate (MTX), it's mode/mechanism of action, the drugs' potential side-effects, use of Folic Acid, patient safety issues and guidance's and monitoring, drug interactions/concomitant medications, screening, BSR/NICE/treat to target

recommendations etc has undoubtedly changed the way and what I advise patients re: MTX.

I update the information to reflect any new advice or research. I also read extensively to gain any useful information from other sources that would be helpful to pass on to patients

Methotrexate was introduced with great caution within Rheumatology. Dosage was not escalated as it is today. We now treat much more aggressively and therefore when educating patients, patients are informed as to the benefits of treating aggressively and the use of Methotrexate alongside other drug regimens which can benefit the outcome / prognosis of their disease depends on the client. if rheum Specialist Nurse has given any updated information it is then incorporated into patient education.

confidence comes with experience,

I have read extensively since joining my trust. I have managed to increase my knowledge in preparing patients for using MTX as a result. I have become more confident and competent, as my understanding and experience has grown. Im learning more about the drug and how it affects different people both good and pass, so I can pass this on I have learned from feedback from patients, fellow practitioners and patient support groups some helpful hints and how they experience taking Methotrexate.

Yes, as I got more confident, I adapt to pts individually and write details into the Methotrexate monitoring booklet which was introduced in 2006 to help pt understanding. This is a new role for me and I am still very much a novice Specialist Nurse within Rheumatology. I have only educated a very small number of patients on Methotrexate so far. The first time I felt very nervous and unsure of myself. I haven't seen enough patients to build on my confidence yet.

It is difficult to answer question 13 below as I have been in my role for less than 12 months. Therefore, I will have to answer that it took me over 1 year to become confident (as I think it probably will take that long). I use to start mtx in low dose and increasing slowly, now pt are able to start at much high dose with close monitoring. I can explain how it works possible side effects, blood monitoring and results I am more inclined to adapt what I say to the patients needs. I am less like to try and persuade someone who does not want treatment but give them all the facts and bring them back to discuss it further.

The education is more formal and we now use a check list that we sign and get the patient to sign ensuring that they have been well informed and making sure that any questions they may have been answered a lot more information, clinical trial evidence, educational events/study days, overall experience, networking with other nurses,

I feel very confident and can draw on past experience and patient stories to aid education

the drug therapy is now licensed unlicensed when i started pts were not allowed to administer their own a Methotrexate clinic was the norm for a long time. Hospital attendance a must. I have more knowledge and understanding of the drug and its actions, more time allocated in clinics for education

I've got more experience in educating patients and have more confidence in my role

When I started I was ward based so many changes have occurred over the last 20 years, growing in confidence the more often you see patients, learning from colleagues initially but now after such a long time and also being an independent prescriber I am quite confident in my approach to counselling.

I have only worked in this department, so I am still in the learning phase, however the way i advise patients had changed as my confidence and knowledge base increases. Knowledge gained from feed back from patients can be passed on to other patients. Have become more confident as my knowledge has improved as my knowledge increased and my confidence grew I found it easier to answer basic questions am now using a

lot of motivational interviewing techniques to help patients understand the need for Methotrexate. I use a lot of my own experience and confidence in teaching patients about Methotrexate.

As I have gained experience my knowledge base has grown

As information on the drug changes or develops so does the education.

I am now more confident and have more knowledge about DMARDs, inflammatory conditions and interpreting blood results. The way Methotrexate is stored is different so we advise the patients about this. (At room temperature). The syringes are now prefilled and the needles are attached and the service is audited with pharmacy who send out periodical questionnaires

We have a home delivery service so more emphasis is placed on data protection as they are outside contractors. Storage safety and disposal of cytotoxic waste is explained in more detail as the home delivery service collect some sharps boxes. We give an information booklet to the patients on home delivery with contact numbers of the coordinator from home delivery and our contact number

Able to summarise key points to remember. Eg infections. Through experience more able to describe the positive benefits of Methotrexate. As my knowledge has increased I have been able to give patients more detailed advice. The more experience I have working with patients on MTX has helped my knowledge base, plus the information patient volunteer helps to build a side effect profile of MTX.

Appendix 11 Participant Information Sheets and Consent Form for Phase I

Northumbria Healthcare NHS
NHS Foundation Trust

A STUDY OF THE LEARNING NEEDS OF NURSES EDUCATING PATIENTS STARTING METHOTREXATE

NURSE Information sheet and Consent form

Protocol Number:	1.0		
Title:	**A STUDY OF THE LEARNING NEEDS OF NURSES EDUCATING PATIENTS STARTING METHOTREXATE**		
Sponsor	Northumbria Healthcare NHS Foundation trust		
Name of Institution:	Northumbria Healthcare NHS Foundation Trust		
Address:	North Tyneside General Hospital, Rake Lane, North Shields, Tyne & Wear NE29 8NH		
Name of Participant:			
	(Last)	(First)	(Title)

Invitation to participate in the study

We would like to invite you to take part in a research study.

What is the purpose of the study?

The purpose of this study is to identify the learning needs of nurses who educate patients prior to the commencement of Methotrexate.

Why have I been invited?

You have been chosen as a possible participant because you educated patients starting Methotrexate for the first time.

Do I have to take part?

Taking part in this study is entirely voluntary and if you decide to take part, you can withdraw your consent regarding the use and disclosure of your health information and leave the study at any time.

What will happen to me if I take part?

The study involves doing a semi-structured interview with nurses who educate patients starting Methotrexate. The interview will be audio-recorded but no identifiable information will be used, we will refer to you as either a study number or use a pseudonym. We would also like to video record the consultation process between the nurse and the patient who is receiving Methotrexate education. If you decide to take part in this part of the study, you will be asked for your consent twice before the recording and you will have the opportunity to withdraw your consent for us to use your video recording after 48 hours, when one of the study team will telephone you to confirm your continued consent. We will invite you to be interviewed by a member of the study team. This interview will involve looking at excerpts from your video and asking for your views and feelings about the education session. The interview will be audio recorded and we will ask for your consent before we start the interview. This interview should take approximately 30 minutes. The interview will then be transcribed but we will delete any personal references to you or use a pseudonym if necessary.

Expenses and payment

You will not be paid to participate in this research study.

What will I have to do?

All you have to do is give your consent for the study team to audio record a semi-structure interview with you and/or video record the education interaction between you and the patient.

What are the possible disadvantages and risks of taking part?

As this is an observational study, with no procedures being performed (apart from being video recorded) there are no foreseen risks or side effects from taking part in the study itself.

You may feel uncomfortable being video recorded, and if this does occur, you may indicate this to the study team who will stop the recording immediately. You may withdraw your consent and the video recording will be destroyed.

What are the benefits of participating in this study?

The data collected during this study will help to improve knowledge and understanding of the needs of nurses educating patients who are starting Methotrexate.

The information gained from this study may help us to better assess the educational needs of nurses which, in the future, which could result in better education provision for nurses and therefore improved overall health care for patients suffering from RA.

What if there is a problem?

In the unlikely event that unprofessional behaviour, dangerous practice or poor education is observed the study team will be available to facilitate the resolution of any problems that we can help with. We will seek further advice if we think you require more support or in the unlikely event that we feel this could be unsafe to patients we will be required to inform your line manager.

If you have a concern about any aspect of the study, you should speak with the study team who will do their best to answer your questions. Contact details can be found at the end of this information sheet. If you remain unhappy and wish to formally complain, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

What will happen if I don't want to carry on with the study?

If you agree to take part in this study and later change your mind, you are free to withdraw your consent and discontinue your participation at any time.

We may withdraw you from the study without your consent for one or more of the following reasons:

- The study is cancelled.
- Unanticipated circumstances.

Will my taking part in this study be kept confidential?

Yes. All the information about you participation in this study will be kept confidential.

You have a right to privacy and all information obtained will be treated as confidential to the limit possible by the law. For the purposes of this study you will be identified by a pseudonym. In this way, if information from the study is submitted to health authorities or published, your name will not appear and your identity will remain confidential.

What will happen to the results of the study?

Your data will be analyzed by the study team. Certain statistical tests will be carried out on your data, along with that collected from the other patients who entered the study. The results may be used in the report of the study or for scientific presentations or publications. You will not be identified by name in any study results. Your doctor will be advised of the results of the study which he can then share with you at your request.

Who is organizing and funding the research?

This study is sponsored by Northumbria Healthcare NHS Foundation Trust and is under the direction of Dr David Walker and research staff. This study has been approved by the Research and Development department who ensures that the rights of people taking part in clinical studies are protected at Northumbria Healthcare NHS Foundation Trust

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Sunderland Research Ethics Committee.

Questions about the study

You can ask your study doctor if you have any questions about the study.

Contact information:

Name: Dr David Walker, Department of Rheumatology - Phone: 08448118111

or Miss Sandra Robinson, Research & Development Department - Phone: 0191 2934322

Address: North Tyneside General Hospital, Rake Lane. North Shields, Tyne & Wear. NE29 8NH

You will be given a copy of this information sheet and a signed consent form to keep.

Thank you for considering this research project

Northumbria Healthcare NHS
NHS Foundation Trust

Study Number:

NURSE CONSENT FORM FOR VIDEO RECORDING A CONSULTATION

Title of study: A Study of the Effectiveness of Nurse Education of Patients Taking Methotrexate.

Name of Researcher:_____

Please initial box

1. **I confirm that I have read and understand the information sheet dated (11th March 2013 V1.1) for the above study and have had the opportunity to ask questions.** ☐
2. **I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and I understand that any data that have been collected up to the point of my withdrawal from the study may continue to be used.** ☐
3. **I agree to a member of the study team contacting me in 48 hours to determine my continued consent to participate in this study.** ☐
4. **I agree to be interviewed at a time which is convenient to me. This interview will be audio-taped and transcribed and will be used for research and education. All indications to my identity will be removed and a pseudonym will be used if necessary.** ☐
5. **I agree that the information generated from my participation in the study may be processed, stored and used for research purposes.** ☐
6. **I understand that if I have any questions relating to my participation in this study, I may contact the study team.** ☐
7. **I agree to take part in the above study.** ☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

Video Recording – Nurse Consent Form

Statement of the Nurse – please read carefully

I understand the reason why the video recording is being taken.

I understand the benefits and risks as described to me by the Study Team.

I understand I can change my mind at any time BUT if recordings are released for teaching it may not be possible to control their future use.

Consent 1 – 15 - 30 minutes pre-recording
I consent to being video recorded and this recording to be used for teaching and research.

Print name……..

Signature ……..….. Date ……../……../……..
(patient or in case of minor, legal guardian)

Consent 2 – At time of recording
I consent to being video recorded and this recording to be used for teaching and research.

Signature ……..….. Date ……../……../……..
(patient or in case of minor, legal guardian)

Statement of responsible Healthcare Professional
I have explained to the nurse the reason for taking the video recording.

I have explained the benefits and risks of making the recording.

Print name …….. Dept …….

Signature …… Date ……../……../…….

Consent 3 - Telephone Consent after 48 hours Taken By:

Signature……..……Time……..…….Date……/……./……

Appendix 12 Study Protocol for Phase II

A STUDY OF THE LEARNING NEEDS OF NURSES EDUCATING PATIENTS STARTING METHOTREXATE

PROTOCOL 1.0

14th December 2012

Dr David Walker

Consultant Rheumatologist

And

Sandra Robinson

Senior Nurse Researcher

North Tyneside Hospital

Telephone 0191 2934322

Table of Contents

1. Background

It is essential before commencing any drug for the patient to understand what the expected benefit is, how that will manifest and to know the risks of the intervention. Indeed this should be part of the decision to prescribe/take the medication. This is especially so for medications such as Methotrexate (MTX) where the effect is delayed and side effects are anticipated and monitored for. Education of patients prior to starting MTX occurs in all Rheumatology units across the country on a daily basis. The purpose of this education is to allow the patient to take the medication more safely and effectively than if it were not given. This includes concording with monitoring requirements. We have demonstrated that knowledge in longer term patients on MTX is deficient in some areas (Walker 2012) and nurses in our units have expressed lack of confidence in giving of this education and described a learning curve when they first started to perform this function. They describe taking time to gain both confidence and competence in drug counselling. This study plans to explore this educational interaction in terms of content, delivery and learning needs for nurses commencing this activity. The purpose is to inform the content of an educational package for the nurse which will make more effective use of their time.

A patient information leaflet for MTX has been produced by ARUK (ARUK 2012). This has been written by experts in the area and contains the important information patients need to be aware of prior to commencing MTX. It is used extensively across the country and the content accepted as appropriate. This forms the basis for patient education in many units.

The literature on the effectiveness of education is largely on change of knowledge with change of behaviour being more difficult to show. Patients with higher educational achievement do however have a better outcome of their RA (Pincus 1985). For patient education about drugs, it has been shown that one to one education results in better adherence (Hill 2001) and that they are more likely to take a drug if they understand the purpose of the prescription (Arluke 1983). How patients wish to receive information, and where from, has been studied in Ankylosing Spondylitis in an ARUK study (Thompson 2010). The main findings were that patients wish to have information at times of change in their condition. This would include times of changing drugs as with commencing Methotrexate therapy. The other time they wish to have information is when their clinical condition changes, usually for the worse ie at times of crisis.

Confidence of nurses giving education

We have been able to identify only one study in the Rheumatology literature on this topic. This was a survey by the Royal College of Nursing (2009) of Rheumatology Specialist nurses, exploring the performance, activity and confidence of Rheumatology Specialist nurses. Two hundred and fifty Rheumatology Specialist nurses, of a variety of different bands (ie working at different levels: Staff Nurses; Sisters and Nurse specialists), were surveyed. When asked about their confidence in counselling a patient starting treatment with Methotrexate, 73%

were very confident ie 27% were less than very confident. It was not clear how this confidence related to seniority and experience. Sixty percent were very confident in dealing with side effects related to anti-rheumatic drugs. Similarly, 60% were confident about educating patients to manage their own disease. A substantial minority of these nurses were, therefore, not very confident in what we would regard as core specialist nursing activities.

This survey measured "perceived" confidence not actual confidence, knowledge and certainly not competence. There was no patient perspective to this survey so we do not know how these educational events are received or how meaningful they are to the patients. In this same survey over 70% of the nurses stated that

a) education regarding drug treatment and

b) education regarding the disease and its management was a major part of their role.

From the broader literature, there are studies showing some evidence that educational interventions can increase nurses' confidence, knowledge and competence. In a study in mental health (Payne 2002), confidence increased in mental health nurses who received mental health training. The nurses were more confident and positive in treating depressed patients. In a study in palliative care (Shipman 2008), there was a statistically significant increase in confidence in palliative care competency and knowledge after participation in an education programme. Similarly, in the treatment of alcohol abuse, there was a statistically significant positive change in nurse confidence levels after a 4 hour educational intervention (Vadlamundi 2008). There is therefore reasonable evidence that the sort of educational package that this study is designed to inform may be beneficial.

2. Aims and Objectives

1) To assess the learning needs of nurses who deliver Methotrexate education to patients, firstly through a broad national questionnaire of such nurses and

2) Secondly through more detailed interviews with nurses of varying experience of this counselling.

3. Detailed Plan of Project

3.1 Introduction

The focus of this study will be on identifying learning needs of nurses who educate patients prior to the commencement of Methotrexate. A pilot study of videoing such consultations will also be undertaken. This will be achieved through a 2 phase study consisting of a specifically developed national questionnaire, semi-structured interview of nurses of varying experience and pilot study of videoing consultations.

Following the mentoring process, the validation of the Methotrexate knowledge questionnaire (MKQ) has been shelved in favour of a national questionnaire of nurses. The focus will be on identifying learning needs through this and the qualitative interviews.

The interviews would provide detailed information on how both participants felt about the interaction with the patient.

3.2 Phase 1

National survey of nurses involved in delivery of patient education prior to commencing Methotrexate (MTX).

A questionnaire which has been specifically developed for nurses performing this role will seek information about the role they have; the training they had prior to commencing it; the evolution of their skills and the perceived learning needs for themselves and new nurses. This has been developed with case scenarios to identify the areas that nurses are less confident in e.g. what action would you propose if a patient has a chest infection etc. This approach measures knowledge and will give us broad high number data that will complement the more detailed information that we will get from the qualitative phase of this project. The clinical scenarios will help to identify the specific areas where there is a deficit in knowledge skills and confidence. Clinical scenarios are likely to include: Nausea; breathlessness; vaccinations: blood abnormalities and alcohol use.

The questionnaire will be available online and as a paper copy. It will be available to any nurse who performs a Methotrexate information giving role with patients, from the most junior and inexperienced to the most senior and most experienced.

The questionnaire will be circulated throughout the UK through the membership of the Royal College of Nursing (RCN) Rheumatology Forum which includes Rheumatology Specialist nurses with a range of experience and seniority. The recruitment target is 80 – 100 completed returned questionnaires to represent the breadth of nurse experience and opinion. If there is less response then we will recruit individual nurses through fora such as the RA special interest group of the British Healthcare Professionals in Rheumatology (BHPR).

The results will be analysed quantitatively and qualitatively as appropriate to provide up to date information on the confidence; training and educational needs of nurses performing this task. It will also give us some indication of knowledge.

3.3 Phase 2

Qualitative interviews with nurses who perform this role

This is a qualitative study that will take place in Newcastle/North Tyneside and Stoke. Nurses willing to take part will be recruited in both centres. It is planned to recruit 3 nurses in two of the study centres, one nurse who has only recently started counselling for Methotrexate and two nurses who have been counselling longer. Semi-structured interviews of 40 to 60 minutes are planned. An interview schedule has been developed to explore in detail the training received prior to starting this function; the experience of delivering it; the evolution of confidence and exploration of experiences. Interviews will be recorded and transcribed verbatim for analysis. Interview data will be analysed using thematic analysis. This is a well recognised method which seeks to identify themes arising from the data.

4. Recruitment Procedures

4.1 Phase 1 Recruitment

The questionnaire will be available to any nurse who performs a Methotrexate information giving role with patients. We are keen to get a full cross section of nurses from the most junior and inexperienced to the most senior and most experienced.

We will identify interested nurses in as many Rheumatology units across the country as possible. We will circulate the membership of the RCN Rheumatology Forum which includes Rheumatology Specialist nurses with a range of experience and seniority. This should produce 80 to 100 responses. This should be sufficient to represent the breadth of nurse experience and opinion. If there is less response then we will recruit individual nurses through forum such as the RA special interest group of the BHPR.

4. Phase 2 Recruitment

Nurses will be identified by the Principal Investigators at two Rheumatology centres. These nurses will be given the staff information leaflet to read before they make a decision to take part in the study. Permission from outpatients' managers will also be sought before any procedures take place.

5. Adverse Event Reporting

5.1 Adverse Events

For all adverse events, the investigator must pursue and obtain information adequate both to determine the outcome of the adverse event and to assess whether it meets the criteria for classification as a serious adverse event (see Section 5.5) requiring immediate notification to the Chief Investigator. For all adverse events, sufficient information will be obtained by the investigator to determine the causality of the adverse event. The investigator is required to assess causality. For adverse events with a causal relationship to

the treatment product, follow-up by the investigator will be carried out until the event or its sequelae resolve or stabilize at a level acceptable to the Chief Investigator.

5.2 Reporting Period

Serious adverse events require immediate notification to the Chief Investigator beginning from the time that the subject provides informed consent, which is obtained prior to the subject's participation in the trial, i.e. prior to undergoing any trial-related procedure and/or receiving and medication, through to and including 28 calendar days after the last administration of the trial medication. Any serious adverse event occurring any time after the reporting period must be promptly reported if a causal relationship to the study medication is suspected.

- Adverse events (serious and non-serious) should be recorded in the CRF from the time the subject has taken at least 1 dose of study medication through to the last subject visit.

5.3 Definition of an Adverse Event

An adverse event is any untoward medical occurrence in a clinical investigation subject administered a product or medical device; the event need not necessarily have a causal relationship with the treatment or usage. Examples of adverse events include but are not limited to:

- Abnormal test findings;
- Clinically significant symptoms and signs;
- Changes in physical examination findings;
- Hypersensitivity;
- Progression/worsening of underlying disease.

Additionally, they may include the signs or symptoms resulting from:

- Drug overdose;
- Drug withdrawal;
- Drug abuse;
- Drug misuse;
- Drug interactions;

- Drug dependency.

5.4 Abnormal Test Findings

The criteria for determining whether an abnormal objective test finding should be reported as an adverse event are as follows:

- Test result is associated with accompanying symptoms, and/or
- Test result requires additional diagnostic testing or medical/surgical intervention, and/or
- Test result leads to a change in trial dosing or discontinuation from the trial, significant additional concomitant drug treatment, or other therapy, and/or
- Test result is considered to be an adverse event by the Chief Investigator.

Merely repeating an abnormal test, in the absence of any of the above conditions, does not constitute an adverse event. Any abnormal test result that is determined to be an error does not require reporting as an adverse event.

5.5 Serious Adverse Events

A serious adverse event or serious adverse drug reaction is any untoward medical occurrence at any dose that:

- Results in death;
- Is life-threatening (immediate risk of death);
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in persistent or significant disability/incapacity.

Medical and scientific judgment should be exercised in determining whether an event is an important medical event. An important medical event may not be immediately life-threatening and/or result in death or hospitalization. However, if it is determined that the event may jeopardize the subject and may require intervention to prevent one of the other outcomes listed in the definition above, the important medical event should be reported as serious.

Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse.

5.6 Hospitalization

Adverse events reported from clinical trials associated with hospitalization or prolongation of hospitalization is considered serious. Any initial admission (even if less than 14 hours) to a healthcare facility meets these criteria. Admission also includes transfer within the hospital to an acute/intensive care unit (e.g. from the psychiatric wing to a medical floor, medical floor to a coronary care unit, neurological floor to a tuberculosis unit).

Hospitalization does not include the following:

- Rehabilitation facilities;
- Hospice facilities;
- Respite care (e.g. care giver relief);
- Skilled nursing facilities;
- Nursing Homes;
- Routine emergency room admissions;
- Same day surgeries (as outpatient/same day/ambulatory procedures).

Hospitalization or prolongation of hospitalization in the absence of a precipitating, clinical adverse event is not in itself a serious adverse event. Examples include:

- Admission for treatment of a pre-existing condition not associated with the development of a new adverse event or with a worsening of the pre-existing condition (e.g. for work-up of persistent pre-treatment lab abnormality);
- Social admission (e.g. the subject has no place to sleep);
- Administrative admission (e.g. for yearly physical examination);
- Protocol-specified admission during a clinical trial (e.g. for a procedure required by the trial protocol);
- Optional admission not associated with a precipitating clinical adverse event (e.g. for elective cosmetic surgery);
- Pre-planned treatments or surgical procedures should be noted in the baseline documentation for the entire protocol and/or for the individual subject.

Diagnostic and therapeutic non-invasive and invasive procedures, such as surgery, should not be reported as adverse events. However, the medical condition for which the procedure was performed should be reported if it meets the definition of an adverse event. For example, an acute appendicitis that begins during the adverse event reporting period should be reported as the adverse event, and the resulting appendectomy should be recorded as treatment of the adverse event.

5.7 Severity Assessment

If required on the adverse event case report forms, the investigator will use the adjectives MILD, MODERATE or SEVERE to describe the maximum intensity of the adverse event. For purposes of consistency, these intensity grades are defined as follows:

MILD	Does not interfere with the subject's usual function.
MODERATE	Interferes to some extent with the subject's usual function.
SEVERE	Interferes significantly with the subject's usual function.

Note the distinction between the severity and the seriousness of an adverse event. A severe event is not necessarily a serious event. For example, a headache may be severe (interferes significantly with the subject's usual function) but would not be classified as serious unless it met one of the criteria for serious adverse events, listed above.

5.8 Causality Assessment

The investigator's assessment of causality must be provided for all adverse events (serious and non-serious). An investigator's causality assessment is the determination of whether there exists a reasonable possibility that the investigational product caused or contributed to an adverse event. If the investigator's final determination of causality in unknown and the investigator does not know whether or not the study medication caused the event, then the event will be handled as "related to the study medication" for reporting purposes. If the investigator's causality assessment is "unknown but not related to the study medication", this should be clearly documented on the trial records.

In addition, if the investigator determines a serious adverse event is associated with trial procedures, the investigator must record this causal relationship in the source documents

and CRF, as appropriate, and report such as assessment in accordance with the serious adverse event reporting requirements, if applicable.

5.9 Withdrawal Due to Adverse Events

Withdrawal due to adverse even should be distinguished from withdrawal due to insufficient response, according to the definition of adverse event noted earlier, and recorded in the appropriate adverse event CRF page.

When a subject withdraws due to a serious adverse event, the serious adverse event must be reported in accordance with the reporting requirements defined below.

5.10 Eliciting Adverse Event Information

The investigator is to report all directly observed adverse events and all adverse events spontaneously reported by the trial subject. In addition, each trial subject will be questioned about adverse events.

5.11 Reporting Requirements

Each adverse event is to be assessed to determine if it meets the criteria for serious adverse event. If a serious adverse event occurs, expedited reporting will follow local and international regulations, as appropriate.

All adverse events will be reported on the adverse events page(s) in the CRF. It should be noted that the form for collection of serious adverse event information is not the same as the adverse event CRF. Where the same data are collected, the forms must be competed in a consistent manner. For example, the same adverse event term should be used on both forms. Adverse events should be reported using concise medical terminology on the CRFs as well as on the form for collection of serious adverse event information.

5.11.1 Serious Adverse Event Reporting Requirements

If a serious adverse event occurs the Chief Investigator is to be notified within 24 hours of awareness of the event. In particular, if the serious adverse event is fatal or life-threatening, notification to the Chief Investigator must be made immediately, irrespective of the extent of available adverse event information. The timeframe also applies to additional new information (follow-up) on previously forwarded serious adverse event reports.

In the rare event that the investigator does not become aware of the occurrence of a serious adverse event immediately (e.g. if an outpatient trial subject initially seeks treatment elsewhere), the investigator is to report the event within 24 hours after learning of it and document the time of his/her first awareness of the adverse event. For all serious

adverse events, the investigator is obliged to pursue and provide information to the Chief Investigator in accordance with the timeframes for reporting specified above. In addition, the Chief Investigator may request specific additional follow-up information in an expedited fashion. This information may be more detailed than that captured on the adverse event case report form. In general, this will include a description of the adverse event in sufficient detail to allow for a complete medical assessment of the case and independent determination of possible causality. Information on other possible causes of the event, such as concomitant medications and illnesses must be provided. In the case of a subject death, a summary of available autopsy findings must be submitted as soon as possible to the Chief Investigator.

5.11.2 Non-serious Adverse Event Reporting Requirements

Non-serious adverse events are to be reported on the adverse event CRFs which are to be submitted to the Chief Investigator.

6. Quality Control and Quality Assurance

During the trial, periodic monitoring will ensure that the protocol and Good Clinical Practices (GCPs) are being followed. Source documents will be reviewed to confirm that the data recorded on CRFs is accurate.

The trial site may be subject to review by the IRB/IEC and/or to inspection by appropriate regulatory authorities.

7. Data Handling and Record Keeping

7.1 Case Report Forms (CRF)

As used in this protocol the term CRF should be understood to refer to a paper form data record.

A CRF is required and should be completed for each included patient. It is the investigator's responsibility to ensure completion and to review and approve all CRFs. CRFs must be signed by the investigator or by an authorized staff member. These signatures serve to attest that the information contained on the CRFs is true. At all times, the investigator has final personal responsibility for the accuracy and authenticity of all clinical and laboratory data entered on the CRFs. Patient source documents are the physician's patient records maintained at the trial site. In most cases the source documents will be the hospital's or the physician's chart. In cases where the source documents are the hospital or the physician's chart, the information collected on the CRFs must match those charts.

In some cases, the CRF may also serve as the source document. In these cases, the Chief Investigator must prospectively document which items will be recorded in the source documents and for which items the CRF will stand as the source document.

7.2 Record Retention

To enable evaluations and/or audits from regulatory authorities the investigator agrees to keep records, including the identity of all participating (sufficient information to link records, e.g. CRFs and hospital records), all original signed informed consent forms, copies of all CRFs, serious adverse event forms, source documents and detailed records of treatment disposition. The records should be retained by the investigator according to International Conference on Harmonization (ACH), local regulations, or as specified in the Clinical Study Agreement, whichever is longer.

8. Communications and publicity

Study results will be discussed in peer reviewed Journals.

9. ETHICS

9.1 Institutional Review Board/Independent Ethics Committee

It is the responsibility of the investigator to have prospective approval of the trial protocol, protocol amendments, informed consent forms and other relevant documents e.g. advertisements, if applicable, from the IRB/IEC. All correspondence with the IRB/IEC should be retained in the Investigator File.

The only circumstance in which an amendment may be initiated prior to IRB/IEC approval is where the change is necessary to eliminate apparent immediate hazards to the subjects.

9.2 Ethical Conduct of the Trial

The trial will be performed in accordance with the protocol, IHC GCP guidelines and applicable local regulatory requirements and laws.

9.3 Subject Information and Consent

The informed consent form must be agreed to by the Chief Investigator and the IRB/IEC and must be in compliance with ICH GCP, local regulatory requirements and legal requirements.

The investigator must ensure that each trial patient, or his/her legally acceptable representative, is fully informed about the nature and objectives of the trial and possible risks associated with participation. The investigator will obtain written informed consent from each patient or the patient's legally acceptable representative before any trial-specific activity is performed. The informed consent form used in this trial, and any changes made

during the course of the trial, must be prospectively approved by both the IRB/IEC and the Chief Investigator before use. The investigator will retain the original of each patient's signed consent form.

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Appendix 13 Example of MIPs Coding Sheets

Behaviour (dependent)	0:00-0:59		Content categories	1:00-1:59		Content categories	2:00-2:59		Content categories
	Nurse	*Patient*		*Nurse*	*Patient*		*Nurse*	*Patient*	
Asks open question									
Asks closed question	IIII		INTRO/Tmt	IIIII	I	Tmt/Med	IIII		Tmt
Gives information	II	I	SEPPE/Tmt	I	III	Tmt / Med	II		Tmt
Gives reassurance	I		SEPPE	I		SEPPE			
Checks information / understanding									
Directs / advises				I		Tmt	IIII		Tmt
Summarises	I		INTRO				I		Tmt
Interrupts	II		TmT						

Behaviour (independent)	0:00-0:59		1:00-1:59		2:00-2:59	
	Nurse	Patient	Nurse	Patient	Nurse	Patient
Orientation / instructions						
Shows agreement / understanding / positive response		IIII		IIIII	II	I
Disagreement / negative response		I		I		II
Positive excalamation			II		I	
Negative exclamation						I
Registers information						
Empathy / support						
Laughs	II	I				II
Asks for repetition					II	
Expresses irritation						
Expresses gratitude						
Expresses apology						
Social conversation / personal remarks	I					
Unintelligible						
Pause						

2019-07-19 17:00 N3 P4

3:00-3:59		Content categories	4:00-4:59		Content categories	5:00-5:59		Content categories	6:00-6:59	
Nurse	*Patient*		*Nurse*	*Patient*		*Nurse*	*Patient*		*Nurse*	*Patient*
|	||	Tmt							|	
|||||	|||	Tmt / Seffs	||||||		Tmt / Seffs	||||		Seffs	|||	| Meal Seffs
|		Seffs	|							
|		Tmt									
			|		Tmt	|||		Seffs / Meal	|	Meal

Each behaviour should be tallied per minute of recording. No content categories are recorded for independent behaviour

3:00-3:59		4:00-4:59		5:00-5:59		6:00-6:59	
Nurse	Patient	Nurse	Patient	Nurse	Patient	Nurse	Patient
				|			
||	|	||	|	|		||||	||
|							|
					||		

2019-07-19 17:00 N3 P4

Content categories	7:00-7:59		Content categories	8:00-8:59		Content categories	9:00-9:59		Content categories
	Nurse	*Patient*		*Nurse*	*Patient*		*Nurse*	*Patient*	
	|		Seffs	|	|	Med		|	Tmt
	||||||	Tests	Seffs | Med	||		Seffs	||||		Tests | Tmt
	|		Med	|||	|	Tests / SEffs	|		Med
	|		Med	|||		Tests | Seffs	|||		Med
				|		Ad / Proc			

Total

	7:00-7:59		8:00-8:59		9:00-9:59	
Patient	Nurse	Patient	Nurse	Patient	Nurse	Patient
	|||	||	||||	|||	||	|
		|				
				|		
		|				
		|	|	|		

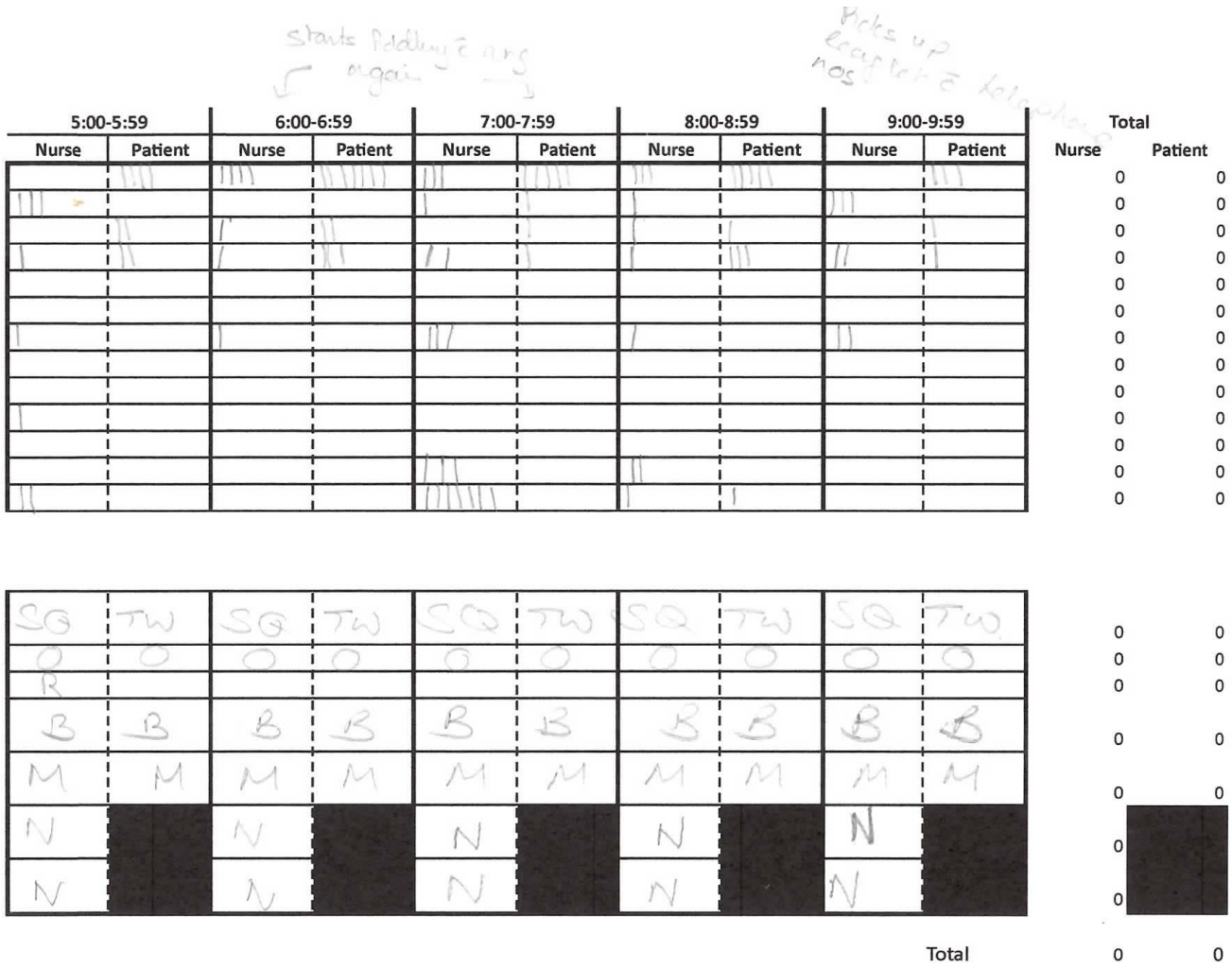
2019-07-19 17:00 N 3 P 4

pt playing w ring (left hand)

Picks up info booklet

Non-verbal behaviour (continuous)	0:00-0:59		1:00-1:59		2:00-2:59		3:00-3:59		4:00-4:59	
	Nurse	Patient	Nurse	Patient	Nurse	Patient	Nurse	Patient	Nurse	Patient
Nodding										
Head shaking										
Smiling										
Touch (self)										
Touch (other)										
Touch (tool)										
Touch (object)										
Point (self)										
Point (other)										
Point (tool) (Pen)										
Point (object)										
Hand gesture (illustrative)										
Hand gesture (batonic)										
Non-verbal kinesic behaviours (dichotomous)	***These categories are general description per each minute grouping (ie general behaviour within the minute). 1 = yes, 0 = no***									
Shoulder position (twisted / square)	SQ	TW	SQ	TW	SQ	TW	SQ	TW	SQ	TW
Posture (closed / open)	O	O	O	O	O	O	O	O	O	O
Hands (busy / relaxed)	R	R	R	B	R	R	R		R	
Body lean (backwards / forwards)	B	B	B	B	B	B	B	B	B	B
Eye contact (maintenance / avoidance)	M	M	M	M	M	M	M	M	M	M
Clinicians: reading / writing (yes / no)	N		Y		Y		Y		Y	
Clinicians: touching patient (yes / no)	N		N		N		N		N	

2019-07-19 17:00 NB P4


5:00-5:59
6:00-6:59
7:00-7:59
8:00-8:59
9:00-9:59
Nurse
Patient
Total
Nurse
Patient
Total
2019-07-19 17:00
N3 P4

Appendix 14 Caldicott Approval Phase III

For office use only			
Ref. no:	C3317	Date Received	

Northumbria Healthcare NHS
NHS Foundation Trust

Use & Release of Personal Identifiable Data (Caldicott Approval Form)

- (Please print clearly)

Introduction

The purpose of the Request for Use or Release of Person-identifiable Data Form is to record the details of identifiable information sent from the Trust to other partners/agencies/organisations. This will ensure that all data flows of personal and/or sensitive information, including healthcare, medical and non-medical, are conducted in a secure and confidential manner and approved by the Trust Caldicott Guardian where necessary.

Division/Directorate: Research and Development

Data Flow Title:
AN EXPLORATION OF THE NURSE/PATIENT CONSULTATION WHEN GIVING INFORMATION ABOUT METHOTREXATE

1) To pilot the use of video in recording this educational interaction for analysis using ethnographic and thematic approaches and in formative ways.
2) To inform the content of an educational package for nurses commencing this activity if appropriate.

The focus of this study will be on identifying learning needs of nurses who educate patients prior to the commencement of Methotrexate. Previous work has been published by the study team. In 2017 (Robinson et al 2017) a national survey of Rheumatology nurses revealed that 84 % of the respondents had some or no training to carry out the role of Methotrexate educator and it could take up to a year for nurses to feel confident in this role. 6 semi-structured interviews were performed on nurses from 2 Rheumatology centres, (Robinson et al 2018) which showed that all participants lacked confidence when starting out on the role of Methotrexate educator, prompts in the form of check lists and booklets were used to ensure that all of the information was given to the patients, and there was little opportunity for patients interactions and questions.
The study team aim to video-record 10 consultations between nurse and patient who are being educated about Methotrexate.
We aim to recruit 4 nurses who will be video-recorded during 2.or 3 methotrexate education sessions in their routine clinics.
We will recruit from one Rheumatology Unit and aim to have nurses at various stages of their experience in order to explore the relationship between experience and knowledge and whether nurses working together pass on information to each other.

Identify purpose:

Healthcare Medical Purpose X (Primary) **Non-Healthcare Medical Purpose ☐ (Secondary)** **Non-Medical Purpose ☐**

For office use only			
Ref. no:		Date Received	

Indicate which data items have been requested:

Forename: ☐ Surname: ☐ DoB: ☐ Age: ☐ Sex: ☐ Address: ☐

Postcode: ☐ NHS No. ☐ Ethnic Origin ☐ Other (please specify) We are video-recording consultations, no other information will be obtained.

Time period for data required: Start date: End date:

Please state regularity e.g. monthly

Trust appointed person/Safe Haven responsible for release of data :

Name: Sandra Robinson Title: Senior research Nurse (Rheumatology)

Division: Corporate Department: Research and Development

Address: Clinical Trials Office, North Tyneside General Hospital.

Telephone: 0191 2934325 Email: Sandra.robinson3@nhct.nhs.uk

Receiving Organisation/individual

Organisation Name: N/A Address:

Appointed person responsible for data: N/A

Contact details: Email address:

Recipients location for receiving and processing Trust data:

NHS Organisation X Government Dept. ☐ UK ☐

EU Country ☐ Non EU Country ☐

Who else will have access to the data?
(If data recipients are not employed by the NHS please state whether NHS honorary contracts are in place. If not – detail confidentiality agreements.)

Members of the Research Team employed by the NHS.

For office use only			
Ref. no:		Date Received	

Method of secure information / data transfer (please tick):

NHSmail.net	☐	Secure fax	☐	Removable media encryption AES 256	☐
Email (secured)	☐	Special Delivery / courier	☐	Electronic File Transfer	☐

Trust Safe Haven .....

Please describe the applicable security arrangements for the transfer: (ie xx@nhs.net to xx@nhs.net)

No data will be transferred out of the Trust. All video recordings will be destroyed once they have been transferred to Trust computers.

How will the service users be contacted?
The patient participants will be identified by their Rheumatology Consultant in clinic at the point when Methotrexate is prescribed. With the potential participant's consent, the study team will post out the Patient Information Sheets pertaining to the study. The potential participant will have the opportunity to ring the study team for more information and arrange a meeting if necessary. If the potential participant agrees to participate in the study, the study team will arrange for that person to be seen by one of the participating nurses.

The nurse participants will be approached directly by the study team as they are known to the nurses. The potential nurse participants will be given nurse information sheets and the opportunity to ask more questions before arriving at a decision on whether they would like to participate.

What information will be given to the service user about the purpose?
All participants will receive Information Sheets explaining the study and their participation in it.

How will the service users consent be obtained?
All participants will be asked to sign a consent form prior to any study procedures being carried out. Consent will be taken by qualified and experienced research personnel.

If no consent being obtained, please detail the reason why not e.g. exemption under Section 251 of the NHS Act 2006.
N/A

How long will the data be stored?
The video recordings on the camera will be deleted when they have been transferred to Trust computers. The recordings on Trust computers will be deleted once they have been analysed. The resultant data will be kept for 15 years in accordance with Trust policy.

Where will the data be physically stored:
On Trust Computers. Resulting analysis data will be kept in the Research Office in the Clinical Trials Department.

If the data is on a computer is there access via a local network or the internet?
The data will not be accessed outside of the Trust.

How will data be protected? (Please detail security measures to be taken)
The Clinical Trials Office is locked at all times. Data will be kept in locked cupboards within the clinical Trials Office.
At the end of this period how will the data be disposed?

Data will be destroyed in accordance with Trust Policy.

For office use only			
Ref. no:		Date Received	

You must address the 7 Caldicott Principles – please give a brief description under each of the following headings

Principle 1 - Justify the purpose(s)
Every proposed use or transfer of service user-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

No identifiable information will be used. All transcripts will be anonymised.

Principle 2 - Don't use service user-identifiable information unless it is absolutely necessary
Service user-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for service users to be identified should be considered at each stage of satisfying the purpose(s).

Service user information will not be used. All identifiable information will be deleted or subjects given pseudonyms.

Principle 3 - Use the minimum necessary service user-identifiable information
Where use of service user-identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.

Only information necessary to complete the study analysis and ensure the robustness of the results will be used.

Principle 4 - Access to service user-identifiable information should be on a strictly need-to-know basis
Only those individuals who need access to service user-identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.

Only the Study team will have access to the video recordings, no identifiable data will be used in any emergent data.

Principle 5 - Everyone with access to service user-identifiable information should be aware of their responsibilities
Action should be taken to ensure that those handling service user-identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect service user confidentiality.

The research team have all had GCP training and have yearly updates and are experienced in the responsibilities and obligations necessary to respect individual patient confidentiality.

Principle 6 - Understand and comply with the law
Every use of service user-identifiable information must be lawful. Someone in each organisation handling service user information should be responsible for ensuring that the organisation complies with legal requirements.

The Principal Investigator has had GCP training and has 13 years' experience in research and will be responsible for ensuring that the research team complies with legal requirements.

Principle 7 - The duty to share information can be as important as the duty to protect patient confidentiality
Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles.

For office use only			
Ref. no:		Date Received	

In the unlikely event that unprofessional behaviour, dangerous practice or poor education is observed the study team will be available to facilitate the resolution of any problems that we can help with. We will seek further advice if we think the participant requires more support or in the unlikely event that we feel this could be unsafe to patients we will inform their line manager.
Other supporting information e.g. Ethics approval, correspondence etc Ethics/HRA and R&D approval has been applied for and is pending. No study procedures will take place until approvals have been given.

For office use only			
Ref. no:		**Date Received**	

I confirm that the data will be held and used according to the conditions and information given as described within this approval from.

Name: SANDRA ROBINSON Title: SENIOR RESEARCH NURSE

Signature: Sandra H Robinson Date: 22/02/19

If the form has been completed by a Medical Student or other similar training posts a supervisory signature or equivalent is required below:

Name:..... Title:.....

Signature:..... Date:.....

Please return the form to:

Deputy Caldicott Guardian **Northumbria Healthcare NHS Foundation Trust:** Tracey Best Head of Performance & Quality 3rd Floor Cobalt Business Exchange & Conference Centre Cobalt Park Way Newcastle upon Tyne NE28 9NZ	**Caldicott Guardian** **Northumbria Healthcare NHS Foundation Trust:** Dr Jeremy Rushmer Executive Medical Director / Consultant in Intensive Care Medicine & Anaesthesia North Tyneside General Hospital Rake Lane North Shields NE29 8NH

For Office Use and Approval Only

Approving Officer please identify the type of data to be provided:

Identifiable Data ☐ Anonymised ☐ Pseudonymised ☐

Approving Officer please identify whether an Information Sharing Protocol or Third Party Data Transfer Agreement is required.

- Information Sharing Protocol Required ☐
- Third Party Data Transfer Agreement Required ☐

The release and use of data as described above: **approved** / **not approved**

Justification :.....

Caldicott Guardian/Delegated Authority signature..... Date: 28/2/19

Recipient copy sent/informed by (name):..... Date:.....

All staff given access to the data will be made aware of these conditions (principle 5)

1. The data will be treated as confidential.
2. The data will be used only for the purposes described.
3. In the case of anonymised or confidential aggregated data, no attempt will be made to identify or contact individuals or organisations identified through these data.
4. The data may be disclosed to staff of the above organisation but only for the purposes described.
5. The data may not be disclosed to any third party.
6. The data will be stored in secure condition at all times whether held on computer medium or as a printed copy.
7. The organisation to which the data are released will maintain and comply with a Data Protection Registration which encompasses the data and data usage described.
8. When the purpose has been completed the data will be securely destroyed in line with NHS approved information destruction/deletion standards (printed copies securely shredded, files securely deleted from computer systems (including any copies held on backup or archive media) and appropriately certificated)
9. Assurance/certificates of secure disposal must be sent to the department above

Appendix 15 Protocol, PIS and Consent Forms Phase III

AN EXPLORATION OF THE NURSE/PATIENT CONSULTATION WHEN GIVING INFORMATION ABOUT METHOTREXATE

PROTOCOL 2.0

22/02/2019

IRAS ID 250427

Dr David Walker and Sandra Robinson

North Tyneside General Hospital

KEY STUDY CONTACTS

Chief Investigator	Dr David Walker/Sandra Robinson Northumbria Healthcare NHS Foundation Trust
Study Co-ordinator	Sandra Robinson
Sponsor	Northumbria Healthcare NHS Foundation Trust North Tyneside General Hospital Rake Lane North Shields NE29 8NH
Key Protocol Contributors	Sandra Robinson Senior Research Nurse 0191 2934325

STUDY SUMMARY

Study Title	An exploration of the nurse/patient consultation when giving information about Methotrexate
Short Title	Nurse/Patient Consultation
Study Design	Observational Single Centre Study
Study Participants	Up to 4 Nurses 10 Patients commencing Methotrexate
Planned Size of Sample (if applicable)	14
Planned Study Period	12 Months
Research Question/Aim(s)	To determine the learning needs of Nurses who education patients commencing Methotrexate

Table of Contents

1. Background

It is essential before commencing any drug for the patient to understand what the expected benefit is, how that will manifest and to know the risks of the intervention. Indeed this should be part of the decision to prescribe/take the medication. This is especially so for medications such as Methotrexate (MTX) where the effect is delayed and side effects are anticipated and monitored for. Education of patients prior to starting MTX occurs in all Rheumatology units across the country on a daily basis. The purpose of this education is to allow the patient to take the medication more safely and effectively than if it were not given. This includes concordance with monitoring requirements. We have demonstrated that knowledge in longer term patients on MTX is deficient in some areas (Walker 2012) and nurses in our units have expressed lack of confidence in giving of this education and described a learning curve when they first started to perform this function. They describe taking time to gain both confidence and competence in drug counselling. This study plans to explore this educational interaction in terms of content, delivery and learning needs for nurses commencing this activity. The purpose is to inform the content of an educational package for the nurse which will make more effective use of their time.

A patient information leaflet for MTX has been produced by ARUK (ARUK 2012). This has been written by experts in the area and contains the important information patients need to be aware of prior to commencing MTX. It is used extensively across the country and the content accepted as appropriate. This forms the basis for patient education in many units.

The literature on the effectiveness of education is largely on change of knowledge with change of behaviour being more difficult to show. Patients with higher educational achievement do however have a better outcome of their RA (Pincus 1985). For patient education about drugs, it has been shown that one to one education results in better adherence (Hill 2001) and that they are more likely to take a drug if they understand the purpose of the prescription (Arluke 1983). How patients wish to receive information, and where from, has been studied in Ankylosing Spondylitis in an ARUK study (Thompson 2010). The main findings were that patients wish to have information at times of change in their condition. This would include times of changing drugs as with commencing Methotrexate therapy. The other time they wish to have information is when their clinical condition changes, usually for the worse ie at times of crisis.

Confidence of nurses giving education

We have been able to identify only one study in the Rheumatology literature on this topic. This was a survey by the Royal College of Nursing (RCN 2009) of Rheumatology Specialist nurses, exploring the performance, activity and confidence of Rheumatology Specialist nurses. Two hundred and fifty Rheumatology Specialist nurses, of a variety of different bands (ie working at different levels: Staff

Nurses; Sisters and Nurse Specialists), were surveyed. When asked about their confidence in counselling a patient starting treatment with Methotrexate, 73% were very confident ie 27% were less than very confident. It was not clear how this confidence related to seniority and experience. Sixty percent were very confident in dealing with side effects related to anti-rheumatic drugs. Similarly, 60% were confident about educating patients to manage their own disease. A substantial minority of these nurses were, therefore, not very confident in what we would regard as core specialist nursing activities.

This survey measured "perceived" confidence not actual confidence, knowledge and certainly not competence. There was no patient perspective to this survey so we do not know how these educational events are received or how meaningful they are to the patients. In this same survey over 70% of the nurses stated that

a) education regarding drug treatment and

b) education regarding the disease and its management was a major part of their role.

From the broader literature, there are studies showing some evidence that educational interventions can increase nurses' confidence, knowledge and competence. In a study in mental health (Payne 2002), confidence increased in mental health nurses who received mental health training. The nurses were more confident and positive in treating depressed patients. In a study in palliative care (Shipman 2008), there was a statistically significant increase in confidence in palliative care competency and knowledge after participation in an education programme. Similarly, in the treatment of alcohol abuse, there was a statistically significant positive change in nurse confidence levels after a 4 hour educational intervention (Vadlamundi 2008). There is therefore reasonable evidence that the sort of educational package that this study is designed to inform may be beneficial.

Pilot study of videoing consultations

Videotaping of consultations has been used extensively for educational purposes in undergraduate (now part of all UK undergraduate curricula with simulated and/or actual patients) and postgraduate medical practice (eg used formatively in UK GP vocational training) as well as in postgraduate nursing practice. In addition, videotaping consultations has been used for research purposes in medical, particularly primary care, settings (reviewed by Coleman 2000) and, less commonly in nurse settings (eg Redsell et al 2004, Collins 2005). Videotaping, if well planned, affords the opportunity of capturing all aspects of the consultation. Coleman (2000) identified a range of research purposes of videotaped consultations in Primary Care, including development of methods of assessing consultation competence, describing doctor-patient communication

quantitatively, exploring how doctors detect and respond to patients with psychological problems, and investigating how patients and doctors view consultations.

A variety of approaches are used in analysing videotaped consultations, including ethnographic approaches which usually incorporate participant observation (Hammersley and Atkinson 2007, Ventres et al 2005), thematic analysis using open coding to identify key themes (Howitt and Cramer 2010; Fereday 2006), and conversation analysis in which consultations are analysed for the use of language, pauses, order of speaking (Maynard and Heritage 2005, Collins 2005). In addition, by showing recordings of the consultation to its participants (health professional or patient), it is possible to gain further insights into interpretations of events and discussions, as well as responses (Coleman 2000).

Despite the potential usefulness of videotaped consultations in the context of nurse education of the Rheumatology patient, there appears a dearth of such work within Rheumatology. As discussed earlier, the Rheumatology nurse constitutes a lynchpin in co-ordinating the care of patients with inflammatory rheumatological diseases. Previous ARUK studies (Carr 2001; Ryan and Adams 2011) have revealed that a significant part of the Rheumatology nurse's work entails counselling patients with respect to treatments. Analysis of such consultations would afford the opportunity of understanding what goes on in these consultations, understanding the responses of patients and nurses to the consultations, and would allow characterisation of nurses' learning needs in this respect. Frameworks for appraising videotaped secondary care nurse consultations do exist (Redsell et al 2004).

2. Aims and Objectives

1) To pilot the use of video in recording this educational interaction for analysis using ethnographic and thematic approaches and in formative ways.

2) To inform the content of an educational package for nurses commencing this activity if appropriate.

3. Detailed Plan of Project

3.1 Introduction

The focus of this study will be on identifying learning needs of nurses who educate patients prior to the commencement of Methotrexate. Previous work has been published by the study team. In 2017 (Robinson et al 2017) a national survey of Rheumatology Specialist nurses revealed that 84 %

of the respondents had some or no training to carry out the role of Methotrexate educator and it could take up to a year for nurses to feel confident in this role. 6 semi-structured interviews were performed on nurses from 2 Rheumatology centres, (Robinson et al 2018) which showed that all participants lacked confidence when starting out on the role of Methotrexate educator, prompts in the form of check lists and booklets were used to ensure that all of the information was given to the patients, and there was little opportunity for patients interactions and questions.

The study team aim to video-record 10 consultations between nurse and patient who are being educated about Methotrexate.

We aim to recruit 4 nurses who will be video-recorded during 2 or 3 Methotrexate education sessions in their routine clinics.

We will recruit from one Rheumatology Unit and aim to have nurses at various stages of their experience in order to explore the relationship between experience and knowledge and whether nurses working together pass on information to each other.

Pilot study of practicality and analysis of videoing the patient education consultation.

(i) Establish a framework for videotaping nurse consultations for research purposes. This would include establishment of strategies for recruitment of patients and nurses, patient consent, and secure storage of recordings.

(ii) Develop a suitable framework for the initial analysis of videotaped consultations and for interviewing participants post video recording of consultations.

(iii) Three to four nurse led clinics will be video-recorded North Tyneside. 10 nurse/patient consultations will be recorded. If the nurse or patient changes their minds, that video recording will be destroyed.

4. Recruitment Procedures

The patient participants will be identified by their Rheumatology Consultant in clinic at the point when Methotrexate is prescribed. With the potential participant's consent, the study team will post out the Patient Information Sheets pertaining to the study. The potential participant will have the opportunity to ring the study team for more information and arrange a meeting if necessary. If the potential

participant agrees to participate in the study, the study team will arrange for that person to be seen by one of the participating nurses.

The nurse participants will be approached directly by the study team as they are known to the nurses. The potential nurse participants will be given nurse information sheets and the opportunity to ask more questions before arriving at a decision on whether they would like to participate.

5. Quality Control and Quality Assurance

During the trial, periodic monitoring will ensure that the protocol and Good Clinical Practices (GCPs) are being followed. Source documents will be reviewed to confirm that the data recorded on CRFs is accurate.

6. Data Handling and Record Keeping

6.1 Case Report Forms (CRF)

As used in this protocol the term CRF should be understood to refer to a paper form data record.

A CRF is required and should be completed for each included patient. It is the investigator's responsibility to ensure completion and to review and approve all CRFs. CRFs must be signed by the investigator or by an authorized staff member. These signatures serve to attest that the information contained on the CRFs is true. At all times, the investigator has final personal responsibility for the accuracy and authenticity of all clinical and laboratory data entered on the CRFs. Patient source documents are the physician's patient records maintained at the trial site. In most cases the source documents will be the hospital's or the physician's chart. In cases where the source documents are the hospital or the physician's chart, the information collected on the CRFs must match those charts.

In some cases, the CRF may also serve as the source document. In these cases, the Chief Investigator must prospectively document which items will be recorded in the source documents and for which items the CRF will stand as the source document.

Data protection and patient confidentiality

The study team will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The recorded consultations will be stored in a locked cupboard in a locked office where only members of the study team have access.

The recordings will be transcribed, and during this process all identifiable data will be

deleted and dedicated study numbers will be used instead.

The recordings will be deleted at the end of the study and all transcriptions will be

stored for up to 15 years in a secure offsite premises in accordance with Northumbria Trust policy.

7. Communications and publicity

Northumbria Healthcare NHS Foundation Trust will own the data arising from the study.

On completion of the study, the recordings will be analysed by the study team. The results of the study will be submitted to an appropriate Journal for publication and will also be offered for presentation at appropriate Rheumatology meetings.

Should any study participants wish to receive the final report, the study team will take their details and send it to them upon completion of the report.

Should any direct quotes from the recordings be used in the final report, they will be completely anonymised so that no identifiable data is used.

8. ETHICS

8.1 Institutional Review Board/Independent Ethics Committee

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Before any subjects are enrolled into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment.

8.2 Ethical Conduct of the Trial

The trial will be performed in accordance with the protocol, IHC GCP guidelines and applicable local regulatory requirements and laws.

The study team consider that there is little risk to the participants in this study. However, should any unethical or potentially harmful behaviour be observed during the recording of the consultation, the individuals concerned will be approached and further action may be taken in the interests of safety should the study team consider this necessary.

An assessment of capacity will take place. The potential participant will:

- understand the purpose and nature of the research
- understand what the research involves, its benefits (or lack of benefits), risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision
- be able to make a free choice
- be capable of making this particular decision at the time it needs to be made

Any person who in the opinion of the study team is considered unable to give fully informed consent, will not be recruited to the study.

The investigator will obtain written informed consent from each patient or the patient's legally acceptable representative before any trial-specific activity is performed.

9. References

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Arthritis Research UK Educational Project Grant Application Form

10.1093/Rheumatology/keq 716

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NURSE INFORMATION SHEET AND CONSENT FORM

Protocol Number:	1.0		
Title:	**AN EXPLORATION OF THE NURSE/PATIENT CONSULTATION WHEN GIVING INFORMATION ABOUT METHOTREXATE**		
Sponsor	Northumbria Healthcare NHS Foundation trust		
Name of Institution:	Northumbria Healthcare NHS Foundation Trust		
Address:	North Tyneside General Hospital, Rake Lane, North Shields, Tyne & Wear NE29 8NH		
Name of Participant:			
	(Last)	(First)	(Title)

Invitation to participate in the study

We would like to invite you to take part in a research study.

What is the purpose of the study?

The purpose of this study is to identify the learning needs of nurses who educate patients prior to the commencement of Methotrexate. This study is part of a PhD project by Sandra Robinson, one of the researchers, who undertook a national survey in 2017 asking nurses how they were educated to teach patients about Methotrexate; most nurses learned on the job, but became confident after about a year. Six nurses were also interviewed, which showed that they were knowledgeable about Methotrexate, but used prompts and checklists which talking to patients about Methotrexate. We feel that formal training would be better but we need to understand what the gaps are so that we can design a learning programme for all nurses who teach patients who are starting Methotrexate therapy. If you would like further information about the previous work, please approach the study team who will be happy to give you the published references.

Why have I been invited?

You have been chosen as a possible participant because you educate patients starting Methotrexate for the first time.

Do I have to take part?

Taking part in this study is entirely voluntary and if you decide to take part, you can withdraw your consent regarding the use and disclosure of your health information and leave the study at any time.

What will happen to me if I take part?

The study involves video recording 2 - 3 consultations between you and the patient to whom you are giving Methotrexate education. You will be asked for your consent before the recordings but you can withdraw your consent and the video-recording will be destroyed. The recordings will be downloaded onto Trust computers as soon as possible after the recordings. Once the recordings have been analysed by the research team, all visual and audio recordings will be destroyed.

Expenses and payment

You will not be paid to participate in this research study.

What will I have to do?

All you have to do is give your consent for the study team to video record the education interaction between you and the patient.

What are the possible disadvantages and risks of taking part?

As this is an observational study, there are no foreseen risks or side effects from taking part in the study itself.

You may feel uncomfortable being video recorded, and if this does occur, you may indicate this to the study team who will stop the recording immediately. You may withdraw your consent and the video recording will be destroyed.

What are the benefits of participating in this study?

The data collected during this study will help to improve knowledge and understanding of the needs of nurses educating patients who are starting Methotrexate.

The information gained from this study may help us to better assess the educational needs of nurses which, in the future, which could result in better education provision for nurses and therefore improved overall health care for patients suffering from RA.

What if there is a problem?

In the unlikely event that unprofessional behaviour, dangerous practice or poor education is observed the study team will be available to facilitate the resolution of any problems that we can help with. We will seek further advice if we think you require more support or in the unlikely event that we feel this could be unsafe to patients we will be required to inform your line manager.

If you have a concern about any aspect of the study, you should speak with the study team who will do their best to answer your questions. Contact details can be found at the end of this information sheet. If you remain unhappy and wish to formally complain, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

What will happen if I don't want to carry on with the study?

If you agree to take part in this study and later change your mind, you are free to withdraw your consent and discontinue your participation at any time.

We may withdraw you from the study without your consent for one or more of the following reasons:

The study is cancelled.

Unanticipated circumstances.

Will my taking part in this study be kept confidential?

Yes. All the information about you participation in this study will be kept confidential.

You have a right to privacy and all information obtained will be treated as confidential to the limit possible by the law. For the purposes of this study you will be identified by a pseudonym. In this way, if information from the study is submitted to health authorities or published, your name will not appear and your identity will remain confidential.

What will happen to the results of the study?

Your data will be analyzed by the study team. Certain statistical tests will be carried out on your data, along with that collected from the other participants who entered the study. The results may be used in the report of the study or for scientific presentations or publications. You will not be identified by name in any study results.

Who is organizing and funding the research?

This study is sponsored by Northumbria Healthcare NHS Foundation Trust and is under the direction of Dr David Walker Consultant Rheumatologist and Sandra Robinson Enior Rheumatology Research Nurse. This study has been approved by the Research and Development department who ensures that the rights of people taking part in clinical studies are protected at Northumbria Healthcare NHS Foundation Trust.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the London - Brent Research Ethics Committee. It has also been reviewed by our colleagues at Northumbria Healthcare NHS Foundation Trust.

Further information and contact details

Northumbria Healthcare NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from your video recording in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Northumbria Healthcare NHS Foundation Trust will keep identifiable information about you for up to 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you wish to withdraw from the study, we will destroy your video-recording. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Individuals from Northumbria Healthcare NHS Foundation Trust and regulatory organisations may look at your research records to check the accuracy of the research study. The Research Team will pass these details to Northumbria Healthcare NHS Foundation Trust along with the information collected from you. The only people in Northumbria Healthcare NHS Foundation Trust who will have access to information that identifies you will be people who may need to contact you to for the purposes of the study or audit the data collection process.

If you would like further information about this study and how we will use your information, please contact Dr David Walker Chief Investigator or Sandra Robinson, on 0191 2934325 during office hours or 07833650925 the Northumbria Healthcare NHS Foundation Trust on-call Rheumatology Research number during out of office and weekends.

Thank you for taking the time to read this information leaflet and do not hesitate to ask any questions before you make a final decision on whether to take par

Study Number:

CONSENT FORM

Title of study: An Exploration of the Nurse/Patient Consultation When Giving Information about Methotrexate

Name of Researcher:_____ Please initial box

_____ _____ _____

I confirm that I have read and understand the information sheet dated 21 March 2019 for the above study and have had the opportunity to ask questions.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and I understand that any data that have been collected up to the point of my withdrawal from the study may continue to be used.	☐
I agree to be video-taped during a Methotrexate Education consultation which will be transcribed and will be used for research and education. All indications to my identity will be removed and a pseudonym will be used if necessary.	☐
I agree that the information generated from my participation in the study may be processed, stored and used for research purposes.	☐
I understand that if I have any questions relating to my participation in this study, I may contact the study team.	☐
I agree to take part in the above study.	☐

Name of Participant Date Signature□

_____ _____ _____

Name of Person taking consent Date Signature

Video Recording –Consent Form

Statement of health professional

I confirm that I have explained the levels of consent to the participant and that they have agreed to have images taken.

Signed:…… Date ……..…….

Name (PRINT) …… Job title……..

You are entitled to withdraw consent to the use of the recordings at any time:

Appendix 16 Ethics and HRA Approvals

NHS
Health Research Authority

London - Brent Research Ethics Committee
80 London Road
Skipton House
London
SE1 6LH

Telephone: 0207 104 8241

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 April 2019

Mrs Sandra Robinson
North Tyneside General Hospital
North Shields
Tyne and Wear
NE29 8NH

Dear Mrs Robinson

Study title:	**An exploration of the Nurse/Patient consultation when giving information about Methotrexate**
REC reference:	**19/LO/0450**
Protocol number:	**N/A**
IRAS project ID:	**250427**

Thank you for your letter of 22 March 2019, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

A Research Ethics Committee established by the Health Research Authority

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe,

they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved Documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper [Covering Letter]		22 February 2019
IRAS Application Form [IRAS_Form_05032019]		05 March 2019
Other [Peer Review]	V1	11 February 2019
Other [CV for Student SR]		19 February 2019
Other [CV David Walker Supervisor]		05 March 2019
Other [Covering letter]		21 March 2019
Other [NHCT patient video consent form]	version 2	01 March 2018
Other [Protocol changes tracked]	version 2	22 February 2019
Participant consent form [NHCT patient Video Consent form]	V2	01 March 2018
Participant information sheet (PIS) [Nurse PIS and Consent form]	Version 2	21 March 2019
Participant information sheet (PIS) [Patient PIS and Consent form]	Version 2	21 March 2019
Participant information sheet (PIS) [Patient PIS and consent form]	Version 2	21 March 2019
Participant information sheet (PIS) [Nurse PIS and consent form]	Version 2	21 March 2019
Research protocol or project proposal [Protocol]	Version 2	22 February 2019
Summary CV for Chief Investigator (CI) [CV CI]		05 March 2019

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/LO/0450	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

PP
Dr Manish Saxena
Chair

Email: nrescommittee.london-brent@nhs.net

Copy to: *Mrs Sandra Robinson*

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mrs Sandra Robinson
North Tyneside General Hospital
North Shields
Tyne and Wear
NE29 8NH

Email: hra.approval@nhs.net

08 April 2019

Dear Mrs Robinson

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**An exploration of the Nurse/Patient consultation when giving information about Methotrexate**
IRAS project ID:	**250427**
REC reference:	**19/LO/0450**
Sponsor	**Northumbria Healthcare NHS Foundation Trust**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **250427**. Please quote this on all correspondence.

Yours sincerely,

Juliana Araujo

Approvals Specialist

Email: hra.approval@nhs.net

Copy to: *Sponsor representative: Mrs Sandra Robinson, Northumbria Healthcare NHS Foundation Trust*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Covering Letter]		22 February 2019
IRAS Application Form [IRAS_Form_05032019]		05 March 2019
Other [Covering letter]		21 March 2019
Other [NHCT patient video consent form]	version 2	01 March 2018
Other [Protocol changes tracked]	version 2	22 February 2019
Other [Peer Review]	V1	11 February 2019
Other [CV for Student SR]		19 February 2019
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Participant information sheet (PIS) [Patient PIS and Consent form]	Version 2	21 March 2019
Participant information sheet (PIS) [Patient PIS and consent form]	Version 2	21 March 2019
Research protocol or project proposal [Protocol]	Version 2	22 February 2019
Summary CV for Chief Investigator (CI) [CV CI]		05 March 2019
2019-03-05 (PRS) Application Valid 19-LO-0450 (IRAS 250427).pdf		05 March 2019
2019-03-20 (PRS) Provisional Opinion 19-LO-0450 (IRAS 250427).pdf		20 March 2019
250427 19 SC 0450_(PRS)_Favourable_Opinion_on_Further_Information_08.04.2019.pdf		08 April 2019

Appendix 17 Trust Capacity and Capability Approval

Dear Sandra

Full Study Title: Nurse Patient Education Videos project

Northumbria Healthcare NHS Foundation Trust is pleased to confirm that we have the capacity and capability to deliver the above study.

Please could you ensure a signed copy of the Capability form/ confirmation emails are saved into the study folder on the X drive.

Many thanks

Jemma

Jemma Fenwick
Deputy Manager of Research & Development
Clinical Trials Office, Education Centre
North Tyneside General Hospital
Rake Lane, North Shields
Tyne & Wear, NE29 8NH

Specific email

Jemma.fenwick@nhct.nhs.net

Generic email

ResearchAndDevelopment@northumbria-healthcare.nhs.uk

From: Robinson Sandra (RTF) NHCT
Sent: 08 May 2019 14:43
To: Fenwick Jemma (RTF) NHCT; Ferguson Victoria (RTF) NHCT
Cc: Heslop Peta (RTF) NHCT
Subject: FW: Nurse Patient Education Videos project

Hi Jemma,

Here are the documents, let me know if you need anything else.

Many Thanks,

Sandra

Senior Research Nurse (Rheumatology)

Clinical Trials Office

Education Centre

North Tyneside General Hospital

Rake Lane

North Shields

Tyne and Wear.

NE29 8NH

Tel: 0191 2934325

Email: sandra.robinson3@nhct.nhs.uk

From: Robinson Sandra (RTF) NHCT
Sent: 09 April 2019 14:25
To: ResearchAndDevelopment
Cc: Fenwick Jemma (RTF) NHCT
Subject: Nurse Patient Education Videos project

Hi Pauline,

I have completed the study capability form for this project. It is not a portfolio study, I don't have any costings to declare and this study will be completely run by myself and David in our own time as it is part of my PhD, there is no involvement from the participants except signing the consent form and no follow up visits, but I have completed the form as fully as possible.

Let me know if there are any other forms I need to complete as soon as you can, as I'd like to get started in the next week or two.

Many Thanks,

Sandra

Senior Research Nurse (Rheumatology)

Clinical Trials Office

Education Centre

North Tyneside General Hospital

Rake Lane

North Shields

Tyne and Wear.

NE29 8NH

Tel: 0191 2934325

Email: sandra.robinson3@nhct.nhs

Appendix 18 The Calgary Cambridge Scoring Sheet

Videos	1	2	3	4	5	6	7	8	9	10	Mean
Initiating why patient here	1	0	2	2	1	2	1	1	2	2	1.4
Setting the agenda	0	0	1	1	1	0	0	0	0	1	0.4
Establishing knowledge	0	0	1	1	2	0	0	1	2	1	0.8
Exploring Ideas Concerns Expectations	0	0	1	0	1	0	0	0	1	0	0.3
Explanation of Content	2	2	2	3	3	2	2	2	3	3	2.4
Chunking & checking of information	0	0	0	0	0	0	0	0	0	0	0
Use of written information	3	2	2	2	2	2	3	2	2	2	2.2
Closing summary of Consultation	1	1	1	0	2	1	0	1	0	1	0.8
Future Plan	2	2	3	2	2	2	2	2	3	2	2.2
Consultation Structure	2	2	3	3	2	2	2	2	3	3	2.4
Clarity of Information	2	2	3	2	3	3	2	3	3	2	2.5
Rapport with the Patient	2	2	2	2	3	2	2	3	3	2	2.3
Empathy with the Patient	1	2	2	2	3	1	1	2	2	2	1.8
Patient perspective addressed	0	1	1	1	1	0	0	1	1	1	0.7
	16	16	24	21	26	17	15	20	25	22	

Appendix 19 The Top Tips for Nurses

TOP TIPS FOR NURSES

Educating people with arthritis about drug treatments.

As a nurse, you play a vital role in helping people with arthritis understand their treatments. Below, we're sharing top tips for educating your patients about the drugs they've been prescribed to treat their condition:

Provide written information to the patient before their appointment.

By giving someone written information before their appointment, you can spend your interview time addressing what the patient wants to talk about.

Set the baseline.

Personalise your approach to the individual patient.

Find out what they already know about their drug treatment and what they want to learn.

Chunk and check.

Present a 'chunk' – or a section – of information.
Then, check to make sure that the patient understands.

For example, you could ask an open question, such as **"What have you understood about what I have told you?"**

Avoid information overload.

Remember that the patient has written information and additional opportunities to learn about their drug treatment. That means that you should not worry if you miss something in your discussion.

However, you should make sure the patient gets the minimum information that they need for their own safety. See 'Minimum information' below.

Let the patient talk.

Do not dominate the conversation, and do not interrupt.

Legitimise the patient's point of view.

Listen and watch.

Make sure that, while you're listening, you pay attention to both verbal and physical cues:

- Is your patient giving you a signal that they want to discuss a topic?
- If you use hand gestures when you talk, make sure they illustrate what you're saying.
- Are you sure that your patient understands? Be aware that nodding is often defensive, not a sign of agreement.
- A patient who appears agitated or who interrupts may not understand what you've told them.

Summarise what you have discussed.

Together with the patient, summarise your conversation.

Ask questions.

You may want to ask, **"What questions do you have?"** and **"How confident do you feel on a scale of one to ten?"**

Give written information.

This should include information about the service, monitoring and any methods to get in touch in between appointments, such as a helpline.

Minimum information

You should always give a patient the following minimum information about their drug treatment.

This is for their safety:

1. **What to take and how to take it.**
   For example, tell the patient the number of tablets they should take and the frequency of the dose.
2. **How long methotrexate takes to work.**
3. **Monitoring requirements.**
   You may need to explain to the patient that, if they do not get monitoring, they cannot take the drug.
4. **Whether changes the patient experiences could be related to the drug.**
   Consult the drug's information leaflet.
5. **Potentially serious issues.**
   For methotrexate, these include infections, fever, shortness of breath and pregnancy.
6. **The helpline number to call if the patient needs assistance.**

Thank you!

Thank you to Sandra Robinson, Senior Nurse Reseacher (Rheumatology) and David Walker, Consultant Rheumatologist, at Northumbria Healthcare NHS Foundation Trust for writing the original text. Thank you also to Alison Kent, Speciality Manager/Nurse Lead – Rheumatology, at Salisbury NHS Foundation Trust who very kindly reviewed the top tips.

If you have any comments or feedback on this publication, please submit them using the following link: **www.surveymonkey.co.uk/r/MTXTopTips**

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Appendix 20 The National Survey Paper

From: Sarah Ryan (RRE) MPFT [mailto:Sarah.Ryan2@mpft.nhs.uk]
Sent: 01 May 2021 07:54
To: Robinson Sandra (RTF) NHCT
Subject: Re: ***EXTERNAL*** adding pdfs of our papers to the appendices of my thesis?

Dear Sandra,

There are no problems with you adding a copy of your journal papers to your appendices. It is great that you have been so proactive with publishing your research

Best wishes

Sarah

From: Robinson Sandra (RTF) NHCT <Sandra.Robinson3@northumbria-healthcare.nhs.uk>
Sent: 30 April 2021 13:53
To: Sarah Ryan (RRE) MPFT <Sarah.Ryan2@mpft.nhs.uk>
Subject: ***EXTERNAL*** adding pdfs of our papers to the appendices of my thesis?

Dear Sarah,

I would like to add pdfs of the three papers I published in Musculoskeletal Care and I would like to check to make sure that the Journal would have no objection to this. Are there any processes I need to go through in order to get permission?

Many Thanks,

Sandra

Sandra Robinson

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DOI: 10.1002/msc.1212

WILEY

RESEARCH ARTICLE

A national survey of nurse training: Confidence and competence in educating patients commencing methotrexate therapy

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Abstract

Introduction: Methotrexate is routinely used to treat active disease in inflammatory arthritis. There have previously been patient safety concerns associated with methotrexate usage in practice. Most patients commencing methotrexate treatment are seen by the rheumatology nurse, to receive education (often referred to as drug counselling) on this agent prior to starting treatment. Yet, there are no recommended criteria regarding education or experience to ensure minimum competence of the rheumatology nurse. The objectives of the present survey were, firstly, to identify the relevant training experience of rheumatology nurses who provide methotrexate education and, secondly, to explore their confidence and competence in undertaking this role.

Method: A national electronic survey of rheumatology nurses, identified via the Royal College of Nursing Rheumatology Forum, national meetings and personal contacts, in order to access nurses who counsel patients on methotrexate, was carried out.

Results: A total of 104 nurses completed the survey. Reported training was highly variable, ranging from very little to having undertaken MSc courses. Knowledge of the drug was rated as the most important requirement. Confidence was largely very good and was reported to develop with experience, with 80% of participants reporting being confident after 1 year in the role. A small number of participants (four) indicated that they were 'not at all confident'. Aspects of competence and knowledge were assessed using questions on clinical situations; knowledge appeared to be good, with the exception of a question on shingles. Confidence correlated with knowledge ($r = 0.21$; $p = 0.05$), amount of training ($r = 0.24$; $p = 0.03$) and most strongly with time in the role ($r = 0.74$; $p = 0.00001$). The amount of training correlated with confidence but not with knowledge. All participants used written information, often using more than one source, with 87% of participants favouring the Arthritis Research UK information leaflet on methotrexate.

Conclusions: There was a wide variety of training for this role. Confidence seemed to come with experience, training and knowledge, and took many months to develop. A training package in this area may be helpful. Reassuringly, confidence and knowledge were related.

KEYWORDS

confidence, methotrexate, nurse education, survey, training

1 | BACKGROUND

The education of patients is a central part of the nursing role in the UK. A survey of rheumatology nurses (Royal College of Nursing, 2009) showed that nurses regularly run educational sessions for newly diagnosed patients, to provide information about their condition, services, treatments and self-management. It is essential for the patient to understand: why they are taking medications, which may contribute to improved medication adherence (Hill, Lewis, & Bird, 2009); what benefits are expected; how long this may take; what side effects may occur, how to minimize any risk of side effects and what to do if these occur. This is particularly true of disease-modifying drugs such as

methotrexate, where the effect is delayed and side effects are not infrequent, and are potentially serious. In 2004, the National Patient Safety Agency (NPSA, 2004) ranked methotrexate as a drug associated with patient safety issues, which further highlights the importance of patient education about this agent. For example, patients need to know what actions to take if they develop breathlessness, have an infection or are planning to have a baby. Routine blood tests are required to identify haematological and biochemical reactions but some side effects cannot be monitored that way and rely on the patient's own surveillance, which reinforces the need for education.

The Nursing and Midwifery Council standards for pre-registration nursing education (Nursing and Midwifery Council, 2010) require student nurses to develop a range of communication skills in order to "acquire, interpret and record their knowledge and understanding of people's needs". The emphasis appears to be on the development of the nurse's own knowledge and not necessarily on developing consultation and teaching skills. These latter skills are often emphasized more in postgraduate courses. Nurses have expressed variable confidence in their educational role (Royal College of Nursing, 2009). The use of methotrexate has increased dramatically over the last 20 years (Butler, Jones, & Hunt, 2006). Discussions with other specialist nurses at national conferences, workshops and meetings have highlighted to the authors that training for nurses performing this role is necessary, often organized locally, and varies in content, but there is a dearth of published material to support this view.

The knowledge that the patient needs to take drugs like methotrexate effectively and safely is contained in patient information leaflets such as that produced by Arthritis Research UK. To educate a patient effectively, a nurse will need to understand this information, have the skills to enable the patient to understand it, and have the knowledge and understanding to answer the patient's questions and recognize concerns that they may not verbalize, as well as provide the opportunity to address any lay beliefs about medications.

The objectives of the present national survey were to identify the training that rheumatology nurses had received for educating patients about methotrexate, to identify their confidence in different aspects of this role and to evaluate their knowledge around clinical situations relevant to methotrexate use, with a view to identifying any need for additional training.

2 | METHODS

A questionnaire was developed using an approach described by Stenner, Carey, and Courtenay (2012). A steering committee was convened to develop the questionnaire, which consisted of a specialist rheumatology nurse, a consultant rheumatology nurse who oversees a drug counselling and monitoring service, two rheumatologists, including one with educational expertise, and an academic rehabilitationist. The questionnaire was designed to identify training, knowledge and confidence in providing information on methotrexate. Knowledge was assessed using 12 single best answer (one from five) scenario-based assessments on clinical situations. Confidence was evaluated by the Likert scale, and prior training was described by the respondents. The questionnaire was then piloted at a regional rheumatology nurse meeting and modified according to the feedback. The modifications were confined to the clinical questions section, where one ambiguous case was removed and two new cases added. The clinical cases focused on scenarios relating to out-of-range blood tests, antibiotics which are not compatible with methotrexate, when to stop methotrexate before pregnancy and what to do in a patient with shingles. These types of scenario are commonly observed in the authors' experience. The survey was then uploaded onto Survey Monkey, a web-based survey tool. A web link to the survey was distributed through the online Royal College of Nursing (RCN) Rheumatology Nurse Forum and the RCN newsletter. It was also sent to potential participants within the UK who were known to the researchers, in order to access as many rheumatology nurses as possible. Participants were asked to forward the link to colleagues with a similar role.

Results were uploaded onto an Excel database and descriptive statistics calculated. Pearson's correlations were calculated to look for correlations between responses on the survey.

3 | RESULTS

A total of 104 nurses undertook the online survey, of whom 77 completed it to the end. The results are given as a percentage of respondents to each given question, as well as the number responding. Seventy-five per cent of respondents described themselves as nurse specialists and 25% of respondents were monitoring nurses. 63.9% (n = 62) of respondents had been teaching patients initiating methotrexate treatment for more than 5 years, 16.5% (n = 16) for 1–5 years, 4.1% (n = 4) for 6–12 months and 15.5% (n = 15) for less than 6 months.

3.1 | Training

Respondents were asked to rank their prior training on a scale from no training, some training or a lot of training, and they were asked to describe any training they had received. Eighty-seven respondents answered this question: 14% (n = 12) had no training prior to starting this role, 70% (n = 61) reported "some training" and 16% (n = 14) had received "a lot of training". For those who had received training, respondents were asked if it was helpful on a scale of no help, some help, moderately helpful or very helpful. Fifty per cent (n = 38) of respondents described it as "very helpful", 22.4% (n = 17) as moderately helpful, 26.3% (n = 20) as of some help and 1.3% (n = 1) as of no help. Sixty-one per cent (n = 53) of respondents expressed that they would have liked more training. In a four-item ranking question asking, "What training do you think nurses need to educate patients about methotrexate", 88% (n = 75) of the 85 participants who completed this question considered that knowledge of methotrexate was needed "a lot". This was followed by communication skills training (73%, n = 62), then consultation skills training (55%, n = 47) and, finally, experience (43%, n = 37).

Seventy-three respondents described the training they had received, which included observing other nurses (31.5%, n = 23), self-directed learning (25%, n = 18) and observing rheumatology clinics (15%, n = 10). The results on training are summarized in Table 1.

TABLE 1 Reported method of training that respondents had prior to commencing their drug counselling role

Main training method	Number of respondents (*n* = 73)
Observing – Other nurses and self-directed	49 (67%)
Observing – Rheumatologist clinics	8 (11%)
In-house chemotherapy course	7 (9.5%)
In-house competencies	4 (5.5%)
Rheumatology course	4 (5.5%)
Prescribing course	1 (1.4%)

3.2 | Confidence

The majority of the respondents (60%) described themselves as "very confident" in this role, with 24% reporting being "confident" and 12% "somewhat confident". Four people were not confident at all. These data are shown in Table 2.

The perceived time it took to become confident in the role was variable, with 13% (*n* = 11) confident in 0–2 months, 45% (*n* = 38) in 3–6 months, 20% (*n* = 17) in a year (a cumulative total of 78% [*n* = 66] of respondents), and for 21% (*n* = 18) of respondents it took over a year. The development of confidence demonstrates that nurses were "learning on the job".

Forty-two per cent reported that their education of patients had changed "a lot" over the time since they had started, and 50% that this had changed "somewhat" while they had been performing the role.

3.3 | Competence/knowledge

This was explored with 12 single best answer questions based on clinical scenarios (Appendix I). There were 90–100% accurate responses to questions about vaccinations, antibiotics and liver function. Questions on alcohol had a mixed response; 40.5% (*n* = 34) of responders thought that 21 units of alcohol per week was acceptable and 50% (*n* = 42) thought that the limit was four units per week. A question on shingles was not well answered, with a range of responses. In regard to a question about pregnancy, opinion was divided between women stopping methotrexate for three months or six months; this is likely to reflect local Trust protocols and changing national guidelines. Nineteen respondents completed only the first half of the survey and a further eight respondents did not complete all of the single best answer questions.

TABLE 2 The confidence of respondents in their role

Confidence level	Number of respondents (*n* = 85)
Very confident	51 (60%)
Confident	20 (24%)
Somewhat confident	10 (12%)
Not at all confident	4 (5%)

3.4 | Written information

A variety of written patient information was reported to be used in educating patients. Different sources of information were often used together. The Arthritis Research UK information sheet was used by 87% (*n* = 74) and judged to be very helpful. Forty-eight per cent (*n* = 41) of respondents used in-house information leaflets, and information produced by the National Rheumatoid Arthritis Society was preferred by 26% (*n* = 22) of respondents. Twenty-seven per cent (*n* = 23) used other information, including the NPSA booklet, RCN booklet, checklists and diagrams.

3.5 | Correlations between confidence and knowledge

Confidence was recorded on a four-point Likert scale and knowledge was assessed by the total score on the clinical questions. Confidence and knowledge correlated positively ($r = 0.29$; $P = 0.008$). Confidence also correlated with the amount of training received ($r = 0.24$; $P = 0.013$) but not with the time that it took to become confident. The correlations are shown in Table 3.

Knowledge correlated with confidence, as noted above, but did not correlate with the amount or usefulness of training, or the time it took respondents to become confident. The amount of training received was correlated with the participants' perception of how useful it was ($r = 0.37$; $P = 0.0006$). There was also a correlation between the amount that the methotrexate educational interaction changed with time, and the amount of time it took for the nurse to become confident ($r = 0.35$; $P = 0.0006$).

Of the nine participants who did not complete all of the knowledge questions, five answered that they were very confident in this role, one was confident, one was somewhat confident and two were not at all confident, of whom one did not attempt any knowledge questions.

TABLE 3 Pearson correlations between confidence, knowledge and other aspects of training

Confidence					
Knowledge	0.21288*				
Amount of training	0.24164*	0.01655		0.13999	−0.09154
Time in education role	0.7425**	0.11293	0.16507		0.17224
Time to become confident	−0.00428	0.07166	−0.09154	0.74252	
	Confidence	Knowledge	Amount of training	Time in education role	Time to become confident

*$P < 0.05$

**$P = 0.00001$

4 | DISCUSSION

There have been few national surveys of nurses' knowledge with regard to their preparedness for the specialist roles which have developed over the past 20 years. In 2001, Latter et al. (2001) recognized that nurses had a potentially important contribution to make towards the education of patients about medications, and carried out a national survey of student nurses on their knowledge of drugs and their attitudes towards patient education. The results demonstrated that there was little opportunity to apply their knowledge and to gain experience, and the attitude seemed to be that they would learn on the job, which, it appears, was exactly what occurred. Courtenay and Carey (2008) carried out a national questionnaire survey of diabetes nurses who were prescribing medication. The aim of the latter survey was to determine how educationally prepared nurses were for prescribing because "there was very little or no evidence on the prescription of medicines by nurses for people with diabetes or whether nurses feel prepared for this role". These authors recognized that nurses had varying levels of expertise and were working in a variety of clinical roles. All nurses surveyed had undertaken a medication prescribing course. Interestingly, of 439 questionnaires analysed, 45% of respondents did not have formal qualification in diabetes; their education had been through study days and in-house training by shadowing a nurse or doctor in their department, which shows a similarity to rheumatology nurse training. The survey found that approximately 50% of the questionnaire participants felt that their needs were not met by the prescribing course they had undertaken.

Surveys have been carried out around perceptions of the rheumatology nurse's role (Goh et al., 2006; Royal College of Nursing, 2009). The present study was the first national survey examining the education and knowledge of nurses in rheumatology who educate patients about methotrexate. It identified great variation in the training for this educational role, and an appetite for more education, including the need for consultation skill training.

Survey Monkey was used as it provides an accessible way of sampling people with questionnaires by simply sending a "link" to potential participants. The content of the questionnaire came from the steering group and was modified from the feedback on the pilot meeting.

The role of the nurse in rheumatology has changed considerably over the past 20 years (Oliver & Leary, 2010). This role has evolved as a result of changing treatments in rheumatology and service provision but the investment in the training of nurses in this role has often been overlooked (Oliver & Leary, 2010). While it is clear that nurses are extremely motivated and will seek out their own information, the present survey showed that there is little accredited and standardized training for nurses in rheumatology regarding the education of patients on methotrexate. Nurses also often find it difficult to get time and funding for any training (Haywood, Pain, Ryan, & Adams, 2013). A recent survey by the Primary Care Respiratory Society UK (2015) on nurse education concluded that: "Nurses will need to be increasingly more resourceful and self-motivated to access training and look beyond traditional study days using innovative methods such as online study and development recording". Courses that enable nurses to access training at a time that suits them, and gain credits for completion, may be popular. In this context, e-learning modules with associated assessment would seem to hold considerable potential. Our results suggest that a module which contains the knowledge base required for the role, including advice on how to aid patient understanding effectively, and also the answers to frequently asked questions, would be a useful addition to practical experience and may shorten the length of time required to achieve confidence and competence.

The observation that confidence was most closely associated with length of time in the role suggests that there is no substitute for experience. Nurses are learning as they work, and the challenge is to shorten the length of time required to become confident with appropriate training and knowledge. The correlations with knowledge and amount of training suggest that it should be possible to increase confidence with better training. It was reassuring, however, that confidence and knowledge were correlated. The New World Kirkpatrick Model (Kirkpatrick, 2016) is the worldwide standard for evaluating the effectiveness of training, and describes the process of behavioural change as a result of knowledge. It is based on the four levels of training evaluation which were developed by Dr Don Kirkpatrick in the 1950s (Kirkpatrick and Kirkpatrick, 2016). The first level, reaction, is the degree to which learners find their training favourable, engaging and relevant; the second level, learning, is the degree of knowledge, skills, attitudes, confidence and commitment that learners acquire, which is based on their participation in the training; behaviour, the third level, relates to the degree to which learners apply what they have learned during the training process; the fourth level, results, relates to the targeted outcomes of that training. These four levels could be applied as best practice to the processes of teaching patients about methotrexate, as follows. Reaction: patients need to be engaged and find the information understandable and relevant; Learning: the evaluation by the nurse to establish how much knowledge the patient has acquired during that teaching process; Behaviour: does the patient take the medication as prescribed, and would they feed back any problems or issues to the nurse; and Results: do patients feel empowered to communicate to the nurse that they have side effects, cannot take their medication as prescribed, and have enough understanding of methotrexate to identify other potentially dangerous problems and report them to the healthcare professional. Further research into the quality of the consultation process and the actual delivery of the learning ("Behaviour" in the Kirkpatrick model) to evaluate the effectiveness of training will be of great interest. This could lead to competence and increased patient safety. Similarly, the evolution of the teaching interaction over time and increasing experience is worthy of further study, to see if the process can be shortened and improved.

4.1 | Limitations of the survey

It was difficult to know if the sample of 104 nurses who started the present survey was typical of nurses who perform this role, but the numbers included specialist, monitoring and research nurses, who would have been the people likely to perform this role. It also included a wide variety of experience and views. It is likely that the participants were more interested and informed than average, but the survey also included people who were not sufficiently confident to complete the knowledge questions. Eighty-five participants started answering the knowledge questions but only 77 participants completed the entire questionnaire.

It could be speculated that participants could have been intimidated by the knowledge questions and chose to close the questionnaire. However, our assessment of knowledge was rudimentary and brief, and the survey was clearly not long enough to make a reliable judgement of respondents' knowledge. Nevertheless, it did serve to give some indication of respondents' understanding of the area as it applies to clinical practice. It may also serve to promote discussion of the assessment of this important area of practice. Involvement of patients in the design of the questionnaire may have raised different types of concern.

5 | CONCLUSION

The nurses included in the present survey showed a great variation in the training they had received prior to undertaking the role of counselling patients starting on methotrexate. The data suggest that those nurses performing the role for the longest period of time had had the least training but there are insufficient published data to support this. Most respondents took 3–12 months to feel confident in this role but, with increasing experience and knowledge, even the most confident nurses continued to change the way they educated patients. Most respondents answered that they would have liked more training, and a training package aimed at satisfying the educational needs of nurses to counsel patients about drugs such as methotrexate could lead to nurses gaining knowledge and confidence with this role, and being able to deliver a competent and comprehensive educational interaction with patients. There is also scope for developing simple assessments of knowledge (perhaps for self-assessment), to help to achieve competence and promote patient safety in this important area of clinical practice.

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Appendix 21 The Semi-Structured Interviews Paper

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RESEARCH ARTICLE

WILEY

An exploration of the experiences of rheumatology nurses counselling patients on methotrexate therapy

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Abstract

Objectives: Methotrexate is commonly used to treat patients with inflammatory arthritis. A key role of a rheumatology nurse is to educate patients on how to take this drug safely prior to the commencement of treatment. The objective of the present study was to explore the experiences of rheumatology nurses conducting this role, focusing on the content of the consultation and training received to perform the role.

Methods: A qualitative phenomenological approach was used. Six semi-structured interviews were performed with nurses from two hospitals who regularly counsel patients prior to starting methotrexate. The interviews were thematically analysed by two researchers and themes extracted.

Results: Four main themes were identified: (a) using written information to structure the content of the consultation; (b) patients have different information needs; (c) time pressures; and (d) training and evolution of practice. All participants described a lack of confidence when they first started counselling patients commencing methotrexate, with a wide variation in training. Participants reported that patients required different information depending on whether they were commencing this agent on its own or in combination with other drugs. All participants experienced some time pressure.

Conclusions: Participants reported that the majority of the consultation focused on conveying information, with little opportunity for patient interaction and questions. We suggest that there is a clear need for further exploration of these consultations, to identify possible training needs. Participants also used standard written information to guide both the structure and content of the consultation limiting patients'; opportunities to ask questions.

KEYWORDS

Nursing, Patient education, Qualitative research

1 | INTRODUCTION

Educating patients prior to starting disease-modifying anti-rheumatic drugs (DMARDs) for inflammatory arthritis is a central role of rheumatology specialist and monitoring nurses (Royal College of Nursing, 2011). In most rheumatology units, once the decision is made by a clinician to commence methotrexate, the patient is then referred to a rheumatology nurse to receive counselling regarding the commencement of treatment (Royal College of Nursing, 2011). Patients need to understand how to take the drug and what side effects to look out for, in order to take it effectively and safely and improve concordance (Hill, Lewis, & Bird, 2009).

Methotrexate is the most widely prescribed DMARD for rheumatoid arthritis and psoriatic arthritis (Bird, Griffiths, & Littlejohn, 2014) and education is particularly important because of its delayed effect and the significant risk of side effects, which can occasionally be fatal (Harrison & Jones, 2014; National Patients Safety Agency, 2004). There are also tolerability problems in

more than half of regular takers, which may affect adherence (Robinson et al., 2015).

No studies have been conducted into to how rheumatology nurses are taught to carry out specialist roles. Latter, Rycroft-Malone, Yerrill, and Shaw (2001) recognized that nurses make an important contribution to the education of patients, and carried out a survey of student nurses to identify drug knowledge and attitudes towards patient education. They concluded that students expected to learn on the job in order to gain knowledge and experience. A survey of diabetic nurses demonstrated that they had not received any formal training to carry out their role (Courtenay & Carey, 2008).

Robinson, Hassell, Ryan, Adams, and Walker (2017) carried out the first survey of rheumatology nurses regarding the training they had received to educate patients on methotrexate. The aims of the survey were to identify knowledge, confidence and perceived requirements for training; the findings demonstrated an historic lack of formal training and variable confidence in the role. Confidence in the role developed over time and was significantly correlated with knowledge. The survey demonstrated that there was little accredited and standardized training for rheumatology nurses regarding the education of patients on methotrexate. The aim of the current study was to explore the experiences of rheumatology nurses counselling patients regarding the commencement of methotrexate therapy, partly as a means of exploring the educational needs of these nurses.

2 | METHODS

A qualitative phenomenological approach was used (Ritchie & Lewis, 2003) because the lived experience of nurses counselling patients on methotrexate use were being explored. Phenomenology looks to examine the real experiences of participants, recognize the qualities of those experiences and therefore identify what is at the core of that experience (Pringle, Drummond, McLafferty, & Hendry, 2011). The goal of phenomenological research is to describe accurately a "lived" experience in relation to what is being studied (Ball, 2009). Further, one of the characteristics of the phenomenology approach is purposive sampling (Connell, McMahon, & Adams, 2014), which ensures that the research question will have a common significance to the research participants. Semi-structured interviews were performed with a purposive sample of six nurses from two rheumatology centres in the UK. The participants were identified by the authors, who were known to them, with the only eligibility criterion being that the participants were involved in the education of patients about to commence methotrexate treatment. This small sample size was in keeping with comparable in-depth qualitative studies where the objective is to gain an in-depth understanding of the experience of particular individuals (Connell et al., 2014; Greenhalgh & Taylor, 1997). A letter of invitation and study information was emailed to all participants. Informed consent was obtained prior to conducting the interview. Ethical approval was obtained from Sunderland Research Ethics Committee.

The interview schedule (Figure 1) was developed by the steering group (which consisted of two rheumatologists, two nurses and an academic psychologist) who had expertise in this area. The interview schedule was also informed by current research which identified the training, confidence and experience of nurses in this role (Robinson et al., 2017).

Demographic details, including the length of time that participants had worked in rheumatology, and that they had been involved in educating patients on methotrexate use, were collected. The interviews

Nurse Interview Schedule

1. Can you describe a recent education session?
   - Do the sessions vary?
   - If they do, in what ways do they vary?
2. Do you use any written information or prompts?
   - Can you describe what you use?
3. Are there some key areas you try to cover when educating patients?
   - Can you describe these?
4. Do patients express their views during these sessions?
   - What are their views?
   - What sort of things do patients talk about?
5. Do you have adequate time to do the education sessions?
   - How much time does it normally take?
6. After the education sessions, do you monitor these patients yourself?
   - How does the monitoring/follow up system work in your department?
7. What preparation did you have before you started educating patients starting Methotrexate?
   - Did you have any supervised practice?
   - What did it consist of?
   - How useful did you find it?
8. In an ideal world what training would you like?
9. How do you feel now about educating patients starting Methotrexate?
   - How confident are you with this role?

FIGURE 1 The interview schedule

were conducted by the lead researcher (S.M.R.). At the beginning of the interview, participants were invited to describe a recent education session that involved counselling a patient on methotrexate use. Their views and experience were sought on: written prompts used during the consultation; key information needed by the patient; patient engagement in the session; duration of the session; training received to counsel patients on methotrexate use; and their confidence in counselling and making arrangements for subsequent monitoring appointments. The interviews took place in a quiet room within the hospital in which the participants worked, and lasted between 45 and 60 min.

Interviews were recorded and transcribed verbatim. Analysis was carried out using a thematic analysis approach which systematically identifies, organizes and offers insight into patterns of themes across a dataset (Braun & Clarke, 2012). In order to control personal bias with regard to analysing the data, the interviews were analysed independently by two researchers (S.M.R., a specialist rheumatology research nurse; and D.W., a consultant rheumatologist), and themes extracted. The transcripts were read to obtain an understanding of the whole experience. Significant statements that were related to the education of patients about methotrexate use were then extracted from the interviews and grouped into themes.

3 | RESULTS

The length of time that the rheumatology nurses had been educating patients on methotrexate use varied from 25 years to 0.5 years. Three of the nurses educated patients immediately following the consultation with a rheumatologist in which they were recommended to start taking methotrexate. The remaining nurses conducted dedicated clinics, with 30-min appointments, to conduct the methotrexate education. Three of the nurses had attended a degree-level rheumatology course, and three had received practical training in the workplace by their nurse colleagues.

The demographic details of the participants are displayed in Table 1.

Four main themes emerged from the data analysis:

1. Using standard written information to structure the content of the consultation
2. Patients have different information needs
3. Time pressures
4. Training and evolution of practice.

3.1 | Theme 1: Using standard written information to structure the content of the consultation

Some participants would commence the consultation by explaining its purposes:

> *I always start off by having the patient reflecting … how they feel their everyday life has been affected by the arthritis and then try and put in context why we are starting methotrexate… (P5)*

> *… when they go to see the doctors, they don't know what they are expecting from us … so we have to discuss why they've come to see me. (P6)*

Other participants tended to start off by explaining what methotrexate is:

> *I usually explain to them that this is a medication that does require blood monitoring. (P3)*

> *I basically go through the booklet. (P2)*

> *I would say, talking about DMARDs, particularly methotrexate … we do follow a chart that we use. (P4)*

All participants had developed a dialogue, using specific information to guide the consultation, to ensure that the information that they felt was necessary to give to the patient was provided:

> *… the purple booklet (local patient information), the methotrexate … and that's … I use that as my prompt … and using it to guide me through and keep me on track, and I seem to have my own little, like, speech and if I get thrown off my speech it sort of throws me a little bit. (P2)*

> *I usually use one of the ARUK leaflets about the … about methotrexate … so that we've got a plan to follow. (P4)*

All of the participants used standard written information and they described underlining or referring to important sections of the information booklets:

> *I normally put a little star by what I think are, for them to take away, important things to be read back … (P4)*

> *I go through the purple booklet (local patient material) and use it to guide me through … it keeps me on track. (P1)*

TABLE 1 Demographic Details of Participants

Participants	Age	Years working in rheumatology	Duration of interview	Previous training
P1	65	25	45	Self-taught
P2	55	1	50	Watched colleagues
P3	48	6	60	Watched colleagues
P4	51	8	45	Mentored by senior colleague
P5	58	14	45	Mentored by senior colleague
P6	35	0.5	50	Mentored by senior colleague

It was apparent that the literature given to the patients often acted as a checklist for the nurse which acted as a prompt during the consultation:

> *I use the headings (of the booklet) and then talk around that subject. (P5)*

> *I go through it you know …. so I know I've said everything I should and then on the back of our … checklist … and it's got everything there like a tick, so I go through that as well, as I am going along. (P6)*

3.1.1 | Sub-theme: Overloading patients with information

Participants volunteered that patients were "bombarded" or "overloaded" with information, and patients were described as being "dazed", "shocked" and "frightened". So, patients were encouraged to take the information booklets and read them again at home, in their own time:

> *… all the information I've just given you is written in this book. Go home and read it again … because it is … it's all there for you to read again, if you … you know … because it is a lot to take in … you know, in 10 minutes … you can't possibly take it all in, so … you know, it's there so go and read it. (P3)*

> *I find that they've been totally bamboozled by the consultant they come out to me and they are a bit sort of dazed, you know, shocked at what they've been diagnosed with, and then I feel as If sometimes I am telling them stuff but they are not actually taking it all on board. (P2)*

> *… they get a little bit frightened … when you talk about it, and some patients just don't want to take drugs. (P1)*

3.1.2 | Sub-theme: Asking questions

It also emerged that patients did not always ask questions during the consultation with the nurse:

> *I would say the majority don't, no, they just sit and take it all in … (P3)*

> *I just didn't have enough time because I thought that she still had questions that she wanted to ask but didn't … (P1)*

But on some occasions, the patients did ask questions:

> *… sometimes they want to know everything in that one sitting and you can't possibly do that… (P4)*

> *I think the people who interrupt are the … the sort of the more, it sounds terrible … but the more intelligent people tend to interrupt and ask more questions. (P3)*

> *How often will I have to come, to have for me … to have my bloods done … that's a main one … I think that's it really… (P6)*

3.1.3 | Sub-theme: Ongoing support

All participants provided patients with the telephone helpline number to use for any follow-up queries following the consultation:

> *… but there is always a helpline, and help at the other end of the phone. (P1)*

> *And we also offer them … the rheumatology advice line number and explain how and when they need to use that… (P4)*

And one centre offered an outreach clinic:

> *… they've got the option of going to an afternoon appointment to one of the outreach clinics but it's still our staff that do them…(P4)*

There were also opportunities for patients to have further counselling when they returned to the monitoring and escalation clinics:

> *…and it's the sessions that they come for monitoring afterwards that they start to get a bit more involved and ask questions there. (P2)*

> *But quite often they do come back to the DMARD escalation clinic. (P3)*

> *When you come for your first monitoring, if you remember anything just write it down, and whoever does the monitoring with you, you know you can ask them. (P6)*

3.2 | Theme 2: Patients have different information needs

It was noted that there were important variations between patients, with respect to their need for information, as perceived by participants:

> *… go into it a little bit deeper than … than others, others just want treatment and no matter what it is as long as they can get rid of their pain … (P1)*

> *… I think, particularly if they are new patients and they've never been on anything before, they have a lot more concerns… (P5)*

The participants described the challenges encountered when counselling patients commencing multiple therapy:

> *Because triple therapy has come out, that's a problem we find … I don't like to bombard people with too much, so doctors like us really to start the triple therapy but you*

might start methotrexate and hydroxyzine, then come back to the sulfasalazine. It's bombarding people and going out and saying, 'Whatever has that nurse said to me?'" (P5)

I do find it hard on the ones who have maybe got … two sets of drugs … you bombard them with two lots… (P2)

The amount of information given to patients varied if they already had some knowledge of their disease and treatment:

… I talked to … about methotrexate. They'd already been on a few DMARDS before, so it was loads easier because they already know the ins and outs of the disease and their condition. (P6)

Sometimes you can fly through … because they seem to have grasped everything you tell them… (P2)

3.3 | Theme 3: Time pressure

Pressures of time were apparent for all participants and appeared to influence how they conducted the consultation:

… because we are under pressure, you know, if you've got a queue of 10, 15 people waiting, you know… (P3)

I mean, for example, if you got a patient that's newly diagnosed and methotrexate is the first DMARD that they've ever come across that they are going to go on to it, I do think you have … you need more time, really, with that patient… (P4)

The participants also said that different patients required different amounts of time:

My honest answer is, I take as much time as it takes … if the patient I feel needs that extra time to go over it and over it, they get it, simple as, because if there is anybody waiting outside, tough, they wait, but I know that we are under that pressure. 'Come on, you know there's a queue' (P2)

There was general agreement that most patients need information spread over several appointments:

… so it becomes an ongoing education session all of the time, or it should be…. (P1)

Don't worry, we will go week to week and we will get there. (P5)

One participant also acknowledged that the patients themselves understood the time pressure and believed that the nurse's time was precious:

I just didn't have enough time because I thought that she still had questions that she wanted to ask but didn't. (P1)

The participants understood that sometimes patients needed time to decide to take the drug:

… so, we leave it open that they can contact us to start it before the review… (P5)

Or may not take it at all:

Some patients just don't want to take drugs … they just don't want them … they just think, well, I will just soldier on with some herbal remedy … but we try to spend time educating them and telling them the safe side … it is a good drug for rheumatoid arthritis (P1).

3.4 | Theme 4: Training and evolution of practice

Most participants felt that when they first started counselling patients on methotrexate, it was an unsettling experience:

… at the beginning, it might frighten you … (P5)

Yes. I mean a lot of the time I'll check with somebody else something that … I know I am doing the right thing but it's just that added reassurance … (P6)

… and although I've had lots and lots of patients … and done lots and lots of monitoring clinics with methotrexate and the other DMARDs, I am still not 100% satisfied that I know enough about that drug for to educate a patient. (P1)

Training to provide education on methotrexate varied between the participants. Some participants had not received any training:

… my training was when we first started using methotrexate … after using things like … drugs like gold and penicillamine mainly and sulfasalazine [there] was none, I didn't have any training whatsoever. (P1)

Other participants described their training as consisting of observing the doctor or nurse:

… I even tried to get sessions where I could go in with the doctor and sort of listen to what they were saying. (P2)

It got clearer when I got on the outpatients because … I didn't start doing the counselling sessions straight off … I sat in with [name of person] a few times… (P6)

All participants described how their practice had evolved with experience and time:

… but then, I think as time goes on, you do, you learn more because you know when you are sitting and monitoring you can … you can hear what other people are telling the patients and so you pick up little snippets. (P3)

… and to me, it's like driving, you can have your lessons, you take your test but you don't really learn

to drive until you are behind that wheel on your own, do you? (P4)

There was agreement between the participants that there was a need to keep up to date as practice evolved:

… and even to this day, I would still say I need to be educated in it further. (P1)

It's like the shingles vaccine; there's been a lot of talk around that. (P5)

One participant described learning about side effects from patients:

… but you still don't learn as much, I don't think, as you do from patients coming in and saying, 'Well I've got this side effect, I've got that side effect'. (P3)

All of the participants agreed that there should be formal training available in order to carry out this role effectively, and offered some suggestions around what they thought could be the content of a training module for nurses new to this role:

…. like, maybe, inhouse training on the computer that I could maybe read and get a background on … (P2)

I think it's good to have a formal session, so that the nurse knows exactly what she is supposed to say, and then as a backup I think the … that role play thing would be good … (P4)

4 | DISCUSSION

The present study explored the experiences of rheumatology nurses educating patients commencing methotrexate treatment. The majority of the consultation focused on nurses imparting information, with little opportunity for patient interaction. Participants recognized that patients had different information needs, which could be challenging to respond to within a time-bound consultation. No standard training was available regarding the knowledge and skills required to perform this role.

The commencement of any medication should be accompanied by some education to enable the patient to know how to take it, how and when it is expected to start working, what side effects to look out for and what, if any, monitoring is required. Hill et al. (2001) demonstrated that educating rheumatology patients on their medication improved concordance. Zhao, Zhao, Wang, Du, and Qin (2015) carried out a survey of 159 patients with coronary heart disease (CDH) in a hospital in China. They assessed medication adherence using the Morisky Medication Adherence Scale (Morisky, Green, & Levine, 1986), and disease knowledge using a Medicine/Disease-Related Knowledge Test (MDKRT). The MDKRT was developed by the researchers with guidance from an expert panel and a systematic literature review (Al Hamarneh, Crealey, & McElnay, 2011). Zhao et al. (2015) concluded that, although the majority of participants had little knowledge of drug treatment, those who had a greater knowledge of CDH were more likely to be drug adherent. Despite the paucity of evidence, guidelines uniformly recommend education (National Institute for Health and Care Excellence, 2013), and the Department of Health (Department of Health, 2012) advocates that health professionals promote self-care and shared decision-making, enabling patients to make choices. This will require the patient to be sufficiently educated, which, in the case of commencing methotrexate treatment, commonly is dependent upon education by nurses who may not necessarily have received education in this area.

During the counselling of a patient on methotrexate use, participants reported discussing the purpose, administration, contraindications and side effects of the treatment; patients then have to make sense of the information given within their own context. The meanings that patients develop will vary, influenced by factors such as their beliefs, past experience, education, culture and intelligence (Goodacre & Goodacre, 2004). It is therefore necessary to check the patient's understanding at frequent intervals.

It was clear that the nurses interviewed understood the purpose of their consultation, but their practice of using a checklist approach to inform the content of the consultation reduced the opportunity for patient to ask questions, and issues that are important to patients and which might have an impact on concordance are unlikely to be discussed. Macdonald et al. (2013) video-recorded 35 consultations between 10 nurses and 18 patients who had type 2 diabetes mellitus. The initial consultation involved the extensive use of checklists and was driven by the nurse's clinical agenda, rather than what the patient already knew or wanted to know. Although checklists can be helpful for the nurse, by ensuring that important information has been delivered to the patient, they might prevent the patient asking the questions that will influence their decision on whether to commence the medication being advocated. The Calgary Cambridge Model is used in many medical schools to teach students how to carry out a consultation (Kurtz, Silverman, & Draper, 2005) and is widely practised among general practitioners (Burt et al., 2013). This model emphasizes the need to provide information in manageable chunks and to use the patient's response to guide the consultation (Kurtz, Silverman, Benson, & Draper, 2003). Although this model was developed for the medical profession, some attempts have been made to apply it in the nursing context (Munson & Willcox, 2007). Nurses who counsel patients about methotrexate use do not necessary need to apply the full model, but elements of it could enhance their consultation skills for this particular role (Munson & Willcox, 2007).

Patients also have different preferences for communication (Macdonald et al., 2013) and, to optimize concordance, the nurse needs to be able to identify the patient's information style preference and meet it. In the present study, nurses were aware of the different needs that patients have but the reliance on the checklist and the time constraints acted as a barrier to responding to these individual needs.

Patients also require information on their condition, to put the treatment into context. Thompson (2009), in a study of patients with ankylosing spondylitis, found that, at disease presentation, before drug therapy commenced, patients wanted responses to a series of questions, which included: "Why have I got it?"; "What will happen to me and my family?"; and "What can I do about it?".

The nurses' perceptions of the limits of time for their consultations appeared to have an impact on their willingness to encourage questions from the patients. Participant 3 used the word "interrupt", which could indicate that this nurse was under time pressure to deliver the methotrexate counselling to the patient, and therefore did not engage in encouraging questions. There was general agreement between the participants that patients did not ask many questions, but there appeared to be little opportunity for them to do this. The nurses described patients as being "bamboozled" or appearing "dazed" and "shocked". Patients in this state would probably find it very difficult to absorb any new information regarding their medication, which appears to be reflected in participant 3's account of patients sitting and "taking it all in" without asking any questions.

Nurses need training to allow them to develop the skills to engage in effective consultations with patients and to increase their confidence in moving away from a checklist consultation. However, it can be difficult to secure study leave and funding for training (Haywood, Pain, Ryan, & Adams, 2013). As drug counselling/education is regarded as a key role of a rheumatology nurse (Royal College of Nursing, 2009), a training programme could be developed. This would include training in effective consultation skills, to maximize the time-bound consultation and increase confidence to enable a two-way communication process without the need for a checklist to structure the consultation, and the encounter can be patient led.

It is difficult to know whether the sample interviewed in the present study was representative of the rheumatology nurse community, and therefore assess the generalizability of the findings, but there is a compelling argument to research further the nature of consultations between nurses and patients. Such research might include direct observation through video recording and postrecording interviews with the participants using video-stimulated recall. This is a method whereby participants are shown video recordings of their own behaviour, in order to stimulate enhanced recall and understanding. This could generate a more meaningful and critical response to that particular consultation event (Paskins, Sanders, Peter, Croft, & Hassell, 2017), thus enriching the data and analysis of the research.

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Appendix 22 The Video Analysis Paper

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RESEARCH ARTICLE

WILEY

An exploratory study using video analysis of rheumatology specialist nurses conducting methotrexate education consultations with patients

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Abstract

Background: Prior to commencing methotrexate, patients routinely attend an education consultation with a rheumatology nurse. The purpose of the consultation is to discuss the patients' expectations and concerns related to commencing methotrexate, the benefits of treatment, potential side effects and monitoring requirements. The aim of this study was to use video analysis to assess the structure, content and mode of delivery of the consultation.

Methods: Video recordings of 10 patient–nurse consultations, involving four specialist rheumatology nurses, were analysed and transcribed. The consultations were compared with the Calgary–Cambridge (CC) consultation model. Transcripts were thematically analysed. Data were quantitatively assessed for verbal and non-verbal behaviours.

Findings: Assessment of the video data using the CC model demonstrated good structure, content and flow of the consultation, influenced by the use of an information leaflet. Consultations generally consisted of communication from nurse to patient rather than a dialogue; the nurse spoke for 69%–86% of the time; clarification of the patient's understanding of the information did not take place in any of the consultations. Thematic analysis also showed that the nurse agenda dominated and the nurse was aware of 'overloading' the patient with information. Cues from the patients to discuss items of importance were often missed.

Conclusion: Video analysis can be used to identify the aspects of the consultation that work well and those areas of the consultation that could be improved with specific training.

KEYWORDS
clinical, communication, education, nursing

1 | INTRODUCTION

Educating patients about their drugs is a central role of the specialist rheumatology nurse (Royal College of Nursing, 2009). Methotrexate is the most frequently initiated disease-modifying antirheumatic drugs (DMARD) for both rheumatoid arthritis (RA) and psoriatic arthritis (PsA). Education about how to take it is particularly important, as the effects are delayed, and side effects can be severe with a small but significant risk of death. Monitoring for side effects is therefore required (Harrison & Jones, 2014).

Traditionally, nurses have been peer-trained to undertake the role of educating patients about methotrexate. A national survey demonstrated that the training rheumatology nurses received was variable, with few nurses having completed any accredited training such as masters' level study (Robinson et al., 2017). Responses suggested that rheumatology nurses perceived that knowledge of methotrexate was the most important requirement for conducting the consultation with no acknowledgement of the need for shared decision making (Robinson et al., 2017). Confidence in educating patients on methotrexate was associated with gaining experience in delivering the consultation rather than informed by patient evaluation. A subsequent interview study of nurses suggested that during the consultation process, nurses focused mainly on giving information, which led to little opportunity for interaction and patient led discussion (Robinson et al., 2018).

There is no national framework to assess the competency of nurses carrying out consultations (Myatt, 2015). All nurses are required to seek professional revalidation every 3 years (Nursing and Midwifery Nursing and Midwifery Council, 2018), but the onus is on the nurse as to the role aspects included in the revalidation, and this does not have to include competency in consultation skills. However, recently the Royal College of Nursing (2020) has published competencies for rheumatology nurses, which are beginning to be implemented into practice.

Consultation models create the framework of the consultation, and most are patient centric (Perry, 2011). Perry recognises that nurses will adapt and formulate their own consultation structure, and seven key elements should be: establishing and maintaining a good rapport, structuring the consultation, obtaining and gathering relevant information, prioritising, clinical reasoning and judgement, and information giving and management planning involving the patient. The Calgary–Cambridge (CC) consultation model (Kurtz & Silverman, 1996) was developed for medical professionals in primary care interactions, and it has been widely adopted in undergraduate and postgraduate teaching of consultation skills. Studies have shown that the CC model can be adapted and applied to consultations conducted by nurse. In China, Yuan et al. (2012) conducted a study with 70 junior nurses; 50% of the nurses were given consultation skills training based on the CC model and 50% were provided with standard learning materials. The nurses who have received training in the CC model demonstrated improvement in observed communication and consultation skills. Donnelly and Martin (2016), in reference to a case study involving a patient receiving chemotherapy for lung cancer, describe how the use of the CC model resulted in more meaningful, empathetic communication between the nurse and patient in the palliative care setting. McLeish and Snowden (2017) acknowledge how the use of the CC model enhanced and provide direction to the consultation. Therefore, the CC model could offer structured guidance for the nurse consultation with patients regarding initiation of treatments such as methotrexate (Munson & Willcox, 2007).

Video recordings provide the opportunity to examine whether a particular consultation model is being used in practice as well as interpreting verbal and non-verbal interactions (Asan & Montague, 2014). Multiple researchers are able to analyse the recordings, thus increasing inter-rater reliability. As recordings can be viewed numerous times, coding from different perspectives can be undertaken (Hiebert et al., 1999). The use of a video camera could be viewed as less intrusive than observation by a physically present individual. Video recordings may be particularly useful in the development of consultation skills with the opportunity for feedback and self-reflection to determine the extent to which shared decision making is integrated into consultations (Royal College of General Practitioners, 2017).

Shared decision-making is a process where patients and healthcare providers consider the various treatment options and patient preferences to reach a health management decision, which is based on mutual agreement (Frosch & Kaplan, 1999). The key principles of shared decision-making involves a process that includes at least two participants, the patient and the healthcare professional. Additionally, this process could incorporate the patient's family and other healthcare professionals. Therefore, the nurse consultation is only part of the shared decision-making process.

2 | AIMS

The main aim of this study was to explore the use of video analysis to observe, assess and inform the process of the nurse–patient interaction.

The second aim was to identify whether there were any specific aspects of the consultation that would benefit from specific training in consultation skills.

3 | METHODS

A convenience sample of 10 consultations by four specialist rheumatology nurses in one rheumatology unit in England was chosen for the study. Data were collected via a mobile video camera that was set up on a tripod and placed in the consultation rooms. Ten videos were considered a pragmatic number for this study. Ethical approval to conduct the study was given by London-Brent Research Ethics Committee.

All patients had inflammatory arthritis and were attending a nurse-run clinic with a view to initiating methotrexate therapy. All were methotrexate naïve.

Patients were approached prior to the consultation, and a written consent was obtained before the video recording. All participants were informed that the video recording could be stopped at any point, or they could withdraw consent and the video recording would be destroyed. Recordings were downloaded and viewed in VLC Media Player, which is a free playback application (Hughey & Maaks, 2020). The recordings were digitally stored on a secure NHS computer system. Transcripts of the complete consultations were typed.

The use of different methods of analysis to develop a comprehensive understanding of a phenomenon is referred to as triangulation (Patton, 1999). In this study, three different analysis methods were adopted: scoring the videos using the CC consultation model (Kurtz & Silverman, 1996); thematic analysis of the video transcripts (Braun & Clarke, 2012) and analysis of the videos using the Medical Interactive Process System (MIPS) (Ford et al., 2000). The use of more than other methods added rigour, richness and depth to the study (Denzin, 2012).

The CC model has five stages and two themes, which run through the consultation (Denness, 2013) (Table 1).

The themes that run throughout the consultation are based on providing structure to the process and build on the relationship with the patient. The CC model meets the seven criteria described by Perry (2011) and has been adapted to be applied in the nursing context and was therefore selected as an appropriate model with which to assess the consultation techniques used by nurses in the video recordings for the study.

4 | ANALYSIS

The recordings were analysed using a framework derived from the CC model categories, except for physical examination, which would not be expected to be performed in these consultations. Each category was scored on a four-point scale:

- 0 = no evidence
- 1 = needs development
- 2 = competent
- 3 = excellent

The timings of all the consultations were available from the recordings, which were scrutinised for the amount of time the nurse and the patient were talking. Correlations between the CC scores and timings were calculated using Pearson correlations.

In addition to the CC model, the MIPS developed by Ford et al. (2000) was also used to code interactions. The basic coding unit of the MIPS is the utterance where each one is coded separately. The MIPS also includes non-verbal categories such as head nodding, eye contact and touch. MIPS has previously been used to analyse the interaction style between physician-led and nurse-led clinics in rheumatology (Vinall_Collier_et_al_2016).

The exploratory method used to explore the data was thematic analysis as the aim of the analysis was to explore the data, identifying specific themes and ideas. A phenomenological approach to the thematic analysis focussed on the human experience, and this methodology is commonly adopted in social sciences (Guest et al., 2012). All of the transcripts were thematically analysed allowing a systematic identification and organisation of patterns of themes across the dataset (Braun and Clarke, 2012). Two researchers (SMR, Rheumatology Nurse Researcher and DW Consultant Rheumatologist) analysed the transcripts separately and discussed any areas of disagreement until inter-coder agreement was reached. All of the transcripts were read multiple times until the whole experience was understood, and then themes were generated. Significant statements relating to the themes were then highlighted to illustrate the themes.

5 | RESULTS

To protect the identity of the nurse participants, minimal demographic data were recorded. The nurses were aged between 30 and 60 years of age. Nurses 1 and 2 (N1 and N2) had 2 years of experience working in rheumatology, Nurse 3 (N3) had 5 years of experience in rheumatology and Nurse 4 (N4) had 20 years of experience working in rheumatology. None of the nurses had undertaken any formal training; they learned from each other and from rheumatologist colleagues, and they attended rheumatology meetings whenever the opportunity arose.

Patients were aged between 25 and 74 years (mean = 51); 8 (80%) were female. Patient demographics are reported in Table 2.

Analysis of the consultations according to the CC scoring system is shown in Table 3

5.1 | Analysis against the Cambridge–Calgary framework

The nurses were competent or excellent in explaining; using written information; planning; structure; clarity and rapport, with mean scores across these categories ranging from 2.2 to 2.5. There was variability in initiating the purpose of the consultation and exhibiting empathy (mean scores 1.4–1.8). In the domains of, setting the agenda; gathering information; checking for understanding; summarising or legitimising the patient perspective, the activity was either not carried out or the nurse was scored as "needing development" (mean scores 0 to 0.8). The total time spent talking during the consultation varied from 12:20 to 23:40 (mean 17:34). The total number of seconds where the nurse or patient was talking is shown in Table 4. The nurse spent 69%–86% of the total time talking, with the patient engaging in discourse for the rest (14%–31%).

TABLE 1 The Calgary–Cambridge consultation model stages and application

The Stages	Application
Initiating the session	Establish a rapport and empathy, legitimise the patient's view
	Establish the reason for the consultation and set an agenda
Gathering information	About current knowledge, ideas, concerns and expectations, where open and closed questions would be used, also picking up on cues
Physical examination	
Explaining and planning	Giving correct amount of information
	Facilitating patient recall and understanding by giving information in chunks and checking for understanding
	Planning using shared decision-making
Closing the session	Include summarising and ensuring that there is an agreed and clear plan

TABLE 2 Patient demographics.

Patient	Age	Male/female	Nurse conducting consultation
P1	62	Female	N1
P2	54	Female	N1
P3	25	Female	N2
P4	27	Female	N3
P5	46	Female	N4
P6	44	Male	N3
P7	72	Female	N1
P8	68	Male	N3
P9	42	Female	N4
P10	74	Female	N2

There was no significant correlation between the total of the CC score and the time the patient spent for talking ($r = 0.5473$, $p = 0.10$), and there was no significant correlation between proportion of the time that the nurse was talking with the CC score ($r = 0.4298$, $p = 0.24$). There was a significant correlation between the proportion of time the patient spent for talking and the length of the consultation ($r = 0.7055$, $p = 0.02$). The total time the consultations took varied in length from 12:42 to 23:54 (mean 17:48); however, it is not clear whether the nurses' perception of time to do the consultations influenced the amount of time they spoke and limited the amount of time the patients had to ask questions.

6 | MIPS ANALYSIS

Using the MIPS analysis, the number of times the patient nodded per minute and the number of times the patients showed agreement or understanding, by responding 'yes' or indicating by a positive 'yeah' were plotted on a chart for all patients. The results are shown in Figure 1.

The thematic analysis of the videos and the transcripts generated three main themes:

1. The Nurse Agenda
2. Information Overload
3. Missed Cues

Theme 1 *The Nurse Agenda*

All of the consultations were structured around the content of the methotrexate information booklet produced by Arthritis (2019). This had the benefit of:

- structuring the encounter;
- dictating the content;
- providing written material.

The typical flow of the consultation is represented in Figure 2.

The focus on delivering all the information in the leaflet dominated all consultations with examples of nurses cutting the patients short and taking the agenda back to the next item in the leaflet.

P9: '…9e'm just worried…in case it interacts between the drugs I take already'.

The patient gives the nurse a list of all of the medications, and the nurse comments:

N4: 'A nice little cocktail…'

Once all of the drugs are recorded, the nurse goes on to say:

N4: 'right, brilliant, brilliant, okay so the Methotrexate is not a painkiller, it's a disease modifying drug…''

Further cues emerge during the consultation:

N4: 'you can't have them…one is called Septrin…''

P9: 'I'm allergic to it..'

N4: '…4allergic to it.. called Sept…'

P9: 'I'm allergic to it…'

N4: 'Perfect, so you are never going to have that problem'

Finally, it emerges during the consultation:

P9: '…they said that about the iron infusion I had as well, I had an anaphylactic shock with that…I nearly died…'

This may be the reason why the patient was so anxious about drug reactions, and the nurse's response appears to demonstrate

TABLE 3 Results of the Calgary–Cambridge analysis

Category	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	Mean
Initiating	1	0	2	2	1	2	1	1	2	2	1.4
Agenda setting	0	0	1	1	1	0	0	0	0	1	0.4
Information/knowledge	0	0	1	1	2	0	0	1	2	1	0.8
Idea/concerns/ expectations	0	0	1	0	1	0	0	0	1	0	0.3
Chunking/checking	2	2	2	3	3	2	2	2	3	3	2.4
Written information	0	0	0	0	0	0	0	0	0	0	
Closing summary	3	2	2	2	2	2	3	2	2	2	2.2
Future plan	1	1	1	0	2	1	0	1	0	1	0.8
Structure	2	2	3	2	2	2	2	2	3	2	2.2
Clarity	2	2	3	3	2	2	2	2	3	3	2.4
Rapport	2	2	3	2	3	3	2	3	3	2	2.5
Empathy	2	2	2	2	3	2	2	3	3	2	2.3
Patient perspective	1	2	2	2	3	1	1	2	2	2	1.8
Picking up cues	0	1	1	1	1	0	0	1	1	1	0.7
Scores	15	16	22	19	25	15	14	19	23	20	18.8

Note. 0, no evidence; 1, needs development; 2, competent; 3, excellent.

TABLE 4 Proportion of time spent talking during the consultation

	Nurse talking s (%)	Patient talking s (%)
Video 1	913 (75)	310 (25)
Video 2	515 (77)	163 (23)
Video 3	950 (80)	237 (20)
Video 4	705 (85)	124 (15)
Video 5	915 (70)	399 (30)
Video 6	654 (85)	118 (15)
Video 7	785 (79)	213 (21)
Video 8	655 (86)	105 (14)
Video 9	761 (69)	341 (31)
Video 10	1055 (74)	365 (26)

that, but this may have taken the nurse out of her sphere of knowledge and confidence, as she remarks:

N4: *'Well, I haven't heard of anybody yet having anaphylaxis…and I don't want to hear about it either'.*

P9: *'No and I'd rather it not be me…'*

In another case, the nurse agenda extended to almost demanding that the patient had an IM steroid when the patient clearly preferred the tablets:

N3: 'do the injections work [steroid injections]…'

P4: 'I haven't had one..'

N3: 'You haven't had one of those? Right..'

P4: 'I didn't fancy one of them'

N3: 'Okay, we could probably do that today…k'

P4: 'I'd really rather have the tablets…'

The nurse acknowledges this, but says:

N3: 'Dr ---- is not actually here today so if I can't get one [a prescription] it might be another option rather than you come off it [oral prednisolone] then go back on it …Okay…have a think about it…'

This exchange appears to have been driven by the difficulty the nurse would have to get a prescription signed for the oral Prednisolone.

Theme 2 *Information overload*

During the consultations, the nurse typically made reference to the (large) volume of information that she had just provided to the patient:

N3: 'Okay, I've just kind of bombarded you there…so if you think of anything else feel free to give me a ring next week and we can explain anything with you…'

N1: 'If I've spoken too fast and you are not too sure then ring…'

P2: 'it's a lot to take in…"

N1: 'Oh there is a lot……'

Further educational opportunities through a helpline were usually offered.

P5: '…if I've got any problems I won't hesitate to give you a call…'

N4: 'It's what we are here for though…'

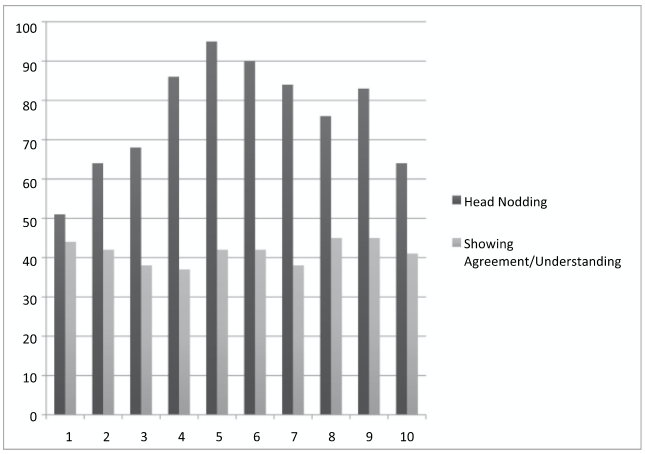

FIGURE 1 Total number of head nodding and agreement per minute for all patients

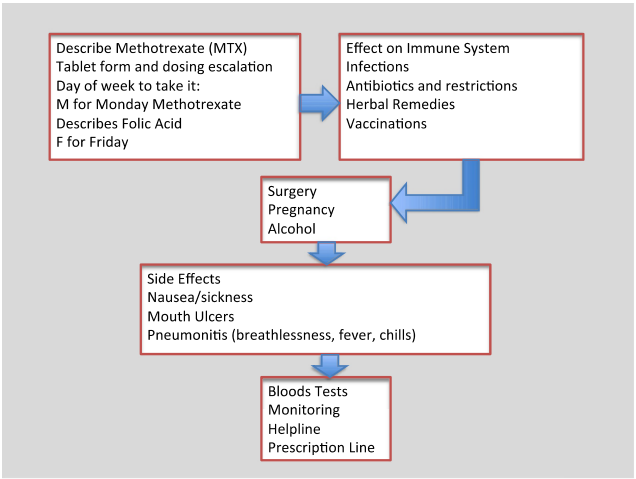

FIGURE 2 The consultation structure

Theme 3 *Missed cues*

The third theme to emerge from the data was missed cues from the patient. Opportunities for the nurse to explore patient cues were missed because the primary objective of the consultation was delivering all the information contained within the drug leaflet:

P1: 'I really want to get off this…I really do want to get off [oral prednisolone]'

N1: 'In terms of your symptoms, how are you doing, have you had any visual disturbances and blurred vision'?

P1: 'I have a cataract…'

N1: 'Right, so, Methotrexate education…'

P2: '…I can't yawn properly…you know when you yawn you open your whole mouth…I can't do that anymore…'

N1: 'Right, so I will give you the prescription and we will see you again in two weeks…but if there's any issues ring the helpline'.

And:

P8: 'I'm doing badly, I mean you do all the training and you don't seem to get any fitter you know….because I was thinking about packing it all in…'

N3: 'Well, lets see how this goes and you might just still be able to do it, alright, where did we get to…'?

However, there were opportunities where the cues are recognised, the nurse is within her sphere of knowledge and experience and deals with cues well:

P9: 'Now with my knees and my joints are just…my fingers…even picking up a pen…'

N4: 'Have you seen an Occupational Therapist'?

P9: 'No, I haven't'.
N4: 'I can refer you there…'
P8: 'I feel like my whole body is breaking down…'
N3: 'Right, so we need to get you some semblance of normality…'

7 | DISCUSSION

Ten nurse consultations were analysed from three different perspectives: comparison with a standard consultation model, the CC model; thematic analysis of the transcripts and detailed examination of head nodding non-verbal behaviours (MIPS analysis).

The results of the video analysis demonstrated that information transfer dominated the interaction. The patients were informed of the important facts and processes, given written information for further reading, and all had a clear invitation to telephone the nurse for further support and clarification. However, it was clear that the patient agenda was not addressed, and cues for further discussion and education were being missed. There is evidence that consultations, which address the patient agenda, result in improved patient satisfaction (Carter & Berlin, 2003).

It is clear that the interaction between the nurse and patient in a Methotrexate education session is complex, and no single method of analysis would be able to evaluate all of this complexity. Therefore, triangulation of the data was used to explore as much of the interaction as possible. The CC model is a proven model for consultations involving the transfer of knowledge. Whilst the model was developed to be used by the medical profession, there is evidence that nurses using this model can improve their communication and interview skills with patients (Yuan et al., 2012).

Donnelly and Martin (2016) recognise that applying the CC model resulted in more meaningful, empathetic communication between the nurse and patient in the palliative care setting. McLeish and Snowden (2017) applied the CC model to illustrate that prescribing decisions can be enhanced and provide direction to the consultation. Applying the CC model resulted in a more meaningful and empathetic consultation between the nurse and patient in the palliative care setting (Donnelly & Martin, 2016) also enhanced decision relating to prescribing medications for patients (McLeish & Snowden, 2017). It is clear from our observations that some important aspects of the CC consultation model were not being applied and that applying them could result in a better consultation.

The consultation was based on the methotrexate information leaflet, which may have led to missed opportunities to recognise cues from the patient. Whilst the study was not able to investigate the reasons for this, it could have been driven by perceived time pressures. The data on the time each participant spent talking suggests that the involvement of the patient, which resulted in higher scoring on the CC scale, added to the length of the overall consultation. It was clear that during each consultation, the type of information given was consistently similar, and took a similar amount of time to deliver; this would explain why the 'extra' involvement of the patient did add some time. However, there is evidence that recognising and dealing with cues can save time by focussing the consultation on the important concerns for patients (Silverman et al., 2016). This may also save time at subsequent visits. It is possible that education and training for nurses in consultation skills could result in more efficient consultations.

The nursing role has expanded over the years, and whilst undergraduate nurse training continues to evolve, it may not be aligned with these emerging roles as the importance of consultation skills does not appear to be a priority in the latest NMC guidelines for nurse training (Nursing and Midwifery Nursing and Midwifery Council, 2018). Over the last 20 years, many specialties, especially those treating patients with chronic disease, have become almost exclusively outpatient based, which has meant that the nurses are now conducting outpatient clinics where communication and consultation skills are essential. Exactly how consultation training should be taught to nurses will merit further study, but Deighan (2011) suggests that consultation teaching is not just about behaviour but also includes attitudes, values and beliefs.

The results of the MIPS analysis show a high degree of head nodding compared to displaying agreement and understanding by the patient. There were numerically almost twice as many head nods as positive utterances, indicating that head nodding alone may not indicate understanding. It is generally considered that head nodding represents showing agreement and understanding (Petukhova & Bunt, 2009; Thepsoonthorn et al., 2016). However, Helweg-Larsen et al. (2004), in a study of students in a classroom situation, made observations which led them to suggest that head nodding reflected a perceived dominance of the teacher over the students. The high level of head nodding behaviour by patients in these situations where the nurse could be viewed as the knowledge holder, and the patient as the knowledge receiver could represent a similar situation where the nurse holds a higher status as the knowledge holder. What could be of particular importance is the nurse's view of this. The nurse may regard this nodding behaviour as confirmation of understanding, which allows them to continue their agenda regarding information giving, without feeling the need to stop to check understanding and may have accounted for some missed cues. Further studies utilising video recordings of nursing consultations could examine this in further depth by using recordings as an interview aid to prompt reflections.

8 | CONCLUSIONS

Video recording has developed into a powerful tool for research in the social sciences (Janík et al., 2009). It allows the study of complex processes and increases inter-rater reliability, and coding from different perspectives can be undertaken (Hiebert et al., 1999). The use of a video camera could also be viewed as less intrusive than a physical presence by the researcher. The video recording allows the whole interaction between nurse and patient to be captured in order to investigate effectiveness of the consultation.

The nurses were good at structuring the consultation, establishing rapport, giving information and instructions, all of which are central nursing skills. The content, flow and chunking of the consultation were consistent, driven by the use of the patient information sheet. The nurses missed opportunities to explore patients' expectations, concerns or needs throughout the consultations. The overarching aim of the consultation was to deliver information, using the Methotrexate information leaflet as a guide. The nurses speaking for between 69% and 86% of the time supports this.

Nurses were variable at assessing pre-knowledge and overlooked openings to evaluate the patient's understanding of information during the consultation. Patient feelings about the drug were sometimes offered by the patient but not often explored by the nurses. Some patient cues were missed. A lot of the patient head nodding may not have reflected understanding (Helweg-Larsen et al., 2004), but it may have encouraged the nurses to perceive this as understanding, which resulted in missed cues.

Whilst limited to 10 video-recordings from one rheumatology service, the findings add weight to the need for rheumatology nurses to receive education in effective consultation skills.

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CONFLICT OF INTEREST

None of the authors have any conflicts of interest.

ETHICAL STATEMENT

Dr. David Walker has undertaken consultancy work for Eli Lilly and Gilead Sciences Ltd, otherwise none of the authors have any conflicts of interest to declare.

AUTHOR CONTRIBUTION

The authors have made their own original contributions to this manuscript and it has not been published elsewhere.

DATA AVAILABILITY STATEMENT

No confidential data can be available from the author upon reasonable request.

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FURTHER READING

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